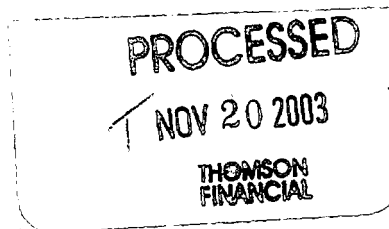
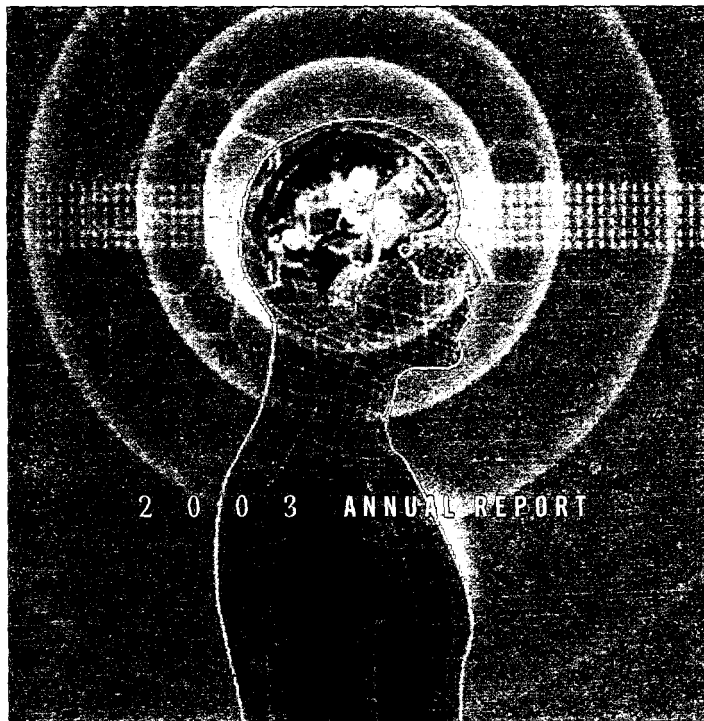
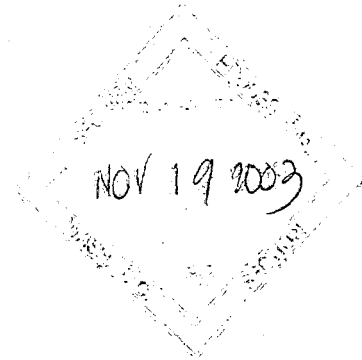




03038273

O-26658  
P.E 6.30-03



L E T T E R

applied our technology to the emerging area of vulnerable plaque, now known to be the most important cause of heart attacks. Antrin® (motexafin lutetium), our lead product candidate in this indication, has completed Phase 1 testing in patients with coronary artery disease. The results of this trial have been presented at major cardiology meetings and were recently published in the journal, *Circulation*. To our knowledge, Antrin is among the first products to be evaluated for treatment of vulnerable plaque and, consequently, is receiving a significant amount of interest from clinicians. Our strategy is to establish a corporate partnership for this drug with a major company focused on development and commercialization of innovative cardiovascular disease products. We currently maintain full worldwide rights to both Antrin and Xcytrin.

Antrin and Xcytrin are just two examples of the diverse applications of our technology platform. It allows us to design and produce drug candidates with novel biochemical properties by making slight modifications to chemical structure. In addition to Xcytrin for oncology and Antrin for atherosclerosis, texaphyrin molecules continue to show promise in other indications. Activity has been demonstrated in preclinical models of HIV and, most recently, in the progressive neurodegenerative disease Amyotrophic Lateral Sclerosis (ALS), often referred to as "Lou Gehrig's disease."

We have the human and financial resources to complete the development of Xcytrin, which remains our focus. We are efficiently managing our cash and believe that we can become a leading oncology company and can successfully commercialize novel oncology products that address serious unmet needs. Compounds in other areas will be licensed to partners when sufficient value has been created, while we focus our resources in oncology.

We embark upon the coming year with a clear vision and strategy for increasing stockholder value. I look forward to updating you on our progress this year as we move Xcytrin closer to market, expand its potential indications and leverage our versatile technology platform to address other important medical needs.



Richard A. Miller, M.D.

President and Chief Executive Officer

## L E T T E R

development of brain metastases, which commonly occur in lung cancer patients. Up to 50% of patients with lung cancer will develop brain metastases. In our previous trial with Xcytrin, 46% of the patients with lung cancer had detectable brain metastases at the time of initial diagnosis of their lung cancer. Patients with brain metastases suffer dreadful neurologic and neurocognitive (ability to think and remember) problems that have a devastating impact on quality of life, family members and health care providers, and impose high costs on the health care system. In fact, clinical research has shown that patients fear the loss of neurologic and neurocognitive function more than any other potential problem associated with a serious illness. Imagine having an illness that leaves you unable to walk or communicate, or unable to recognize or remember your loved ones.

Pharmacylics and a worldwide network of approximately 100 leading medical centers are now conducting the **SMART** trial intended to prove that Xcytrin improves neurologic and neurocognitive outcomes in patients with lung cancer. The **SMART** trial was reviewed and approved through the FDA Special Protocol Assessment procedure. The **SMART** trial is a pivotal trial designed to lead to approval for Xcytrin to prolong time to neurologic progression in patients with brain metastases from lung cancer, should the trial be successful. We and the participating clinical investigators are excited about this trial because of the previous results obtained with Xcytrin for this indication and the knowledge and expertise that we have established in clinical development, brain metastases clinical research and neurologic outcomes assessments. Enrollment in the **SMART** trial is on track for planned completion by the end of calendar 2004.

Our experience and confidence in Xcytrin, the body of published scientific and clinical evidence that now exists for this agent, and the interest shown from numerous clinicians have encouraged us to expand its potential uses to a variety of other cancers. Xcytrin is a unique product opportunity in oncology with the potential to be used in a wide range of clinical situations and in a variety of cancers. We have launched several Phase 1 and 2 clinical trials evaluating Xcytrin either as a single agent or in combination with antibodies, radiation and/or chemotherapy for many cancers including lung, head and neck, prostate, breast, ovarian, primary brain tumors and lymphomas and leukemias. Some of these studies will be generating clinical data in late 2003.

Beyond Xcytrin, our proprietary texaphyrin technology platform continues to exhibit remarkable versatility, allowing us to generate a diverse range of product candidates. In addition to oncology, our primary focus, we have

## L E T T E R

**Dear Stockholders:**

I am very pleased to update you on our progress at Pharmacyclics. We have focused our resources on our late stage investigational product, Xcytrin® Injection (motexafin gadolinium), now in a pivotal Phase 3 trial. By initiating other clinical trials with Xcytrin in several cancer types, we have leveraged our clinical development strengths and increased the chances for success with this product. We have moved forward other compounds generated from our versatile technology platform that have produced promising results in early clinical and preclinical studies. And we have efficiently managed our cash.

During this year, we initiated enrollment in our pivotal Phase 3 **SMART** (Study of Neurologic Progression with Motexafin Gadolinium And Radiation Therapy) trial of Xcytrin in non-small cell lung cancer patients with brain metastases, (i.e., cancer that has spread to the brain from another part of the body).

The **SMART** trial was designed with input from a number of leading clinical experts and with substantial involvement of the FDA. The rationale for the design of the **SMART** trial was based on results of our recently completed 401-patient randomized controlled trial in brain metastases, published in the July 2003 issue of the *Journal of Clinical Oncology*, the official journal of the American Society of Clinical Oncology. Widely considered to be one of the most comprehensive and rigorous clinical studies ever performed in brain metastases, this trial demonstrated consistent benefit in several measurements of neurologic outcomes in patients with lung cancer receiving Xcytrin. We believe that the physicians participating in the study have demonstrated that Xcytrin has the potential to make a major impact in oncology.

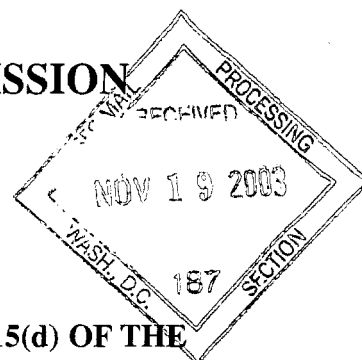
Epidemiologic estimates for the year 2000 demonstrate that lung cancer was the most common cancer in the world, both in terms of incidence (1.2 million new cases worldwide, 164,000 new cases in the United States) and mortality (1.2 million deaths worldwide, 156,900 deaths in the United States). Moreover, lung cancer is expected to remain the leading cause of morbidity and mortality from cancer for decades to come. Unfortunately, newer therapies have not made a significant impact on mortality and patients with lung cancer continue to suffer serious morbidity. One of the most devastating of all cancer related complications is the

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

For Annual and Transition Reports Pursuant to  
Section 13 or 15(d) of the Securities Exchange Act of 1934



☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

For the Fiscal Year Ended June 30, 2003

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES AND EXCHANGE ACT OF 1934**

For the Transition Period From \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 000-26658

**PHARMACYCLICS, INC.**

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

94-3148201

(I.R.S. Employer Identification No.)

995 E. Arques Avenue, Sunnyvale, CA

(Address of principal executive offices)

94085-4521

(Zip code)

Registrant's telephone number, including area code: (408) 774-0330

Securities registered pursuant to Section 12(b) of the Act:

Title of each class

None

Name of each exchange  
on which registered

None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, \$.0001 Par Value

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of Form 10-K or any amendments to this Form 10-K. ☒

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes ☐ No ☒

The aggregate market value of the voting stock held by nonaffiliates of the Registrant as of December 31, 2002, was approximately \$56,153,000 based on the closing price of the Common Stock of the Registrant as reported on the Nasdaq Stock Market on such date. The number of outstanding shares of the Registrant's Common Stock as of August 31, 2003 was 16,238,434.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the following document are incorporated by reference into Part III of this Form 10-K: the Proxy Statement for the Registrant's 2003 Annual Meeting of Stockholders scheduled to be held on December 11, 2003.

[This page intentionally left blank.]

**ANNUAL REPORT ON FORM 10-K  
FOR THE FISCAL YEAR ENDED JUNE 30, 2003**

**TABLE OF CONTENTS**

	<u>Page</u>
<b>PART I</b>	
Item 1. Business .....	1
Item 2. Properties .....	20
Item 3. Legal Proceedings .....	20
Item 4. Submission of Matters to a Vote of Security Holders .....	20
<b>PART II</b>	
Item 5. Market for Registrant's Common Equity and Related Stockholder Matters .....	21
Item 6. Selected Financial Data .....	22
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations .....	23
Item 7A. Quantitative and Qualitative Disclosures About Market Risks .....	28
Item 8. Financial Statements and Supplementary Data .....	29
Item 9. Changes in and Disagreements With Auditors on Accounting and Financial Disclosure .....	47
Item 9A. Controls and Procedures .....	47
<b>PART III</b>	
Item 10. Directors and Executive Officers of the Registrant .....	48
Item 11. Executive Compensation .....	48
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters .....	48
Item 13. Certain Relationships and Related Transactions .....	48
<b>PART IV</b>	
Item 14. Principal Accountant Fees and Services .....	49
Item 15. Exhibits, Financial Statement Schedules, Exhibits and Reports on Form 8-K .....	49
Signatures .....	52

[This page intentionally left blank.]



## Part I

### Item 1. *Business*

We are a biopharmaceutical company developing a patented new class of drugs to treat cancer and atherosclerosis. Our pharmaceutical agents, known as texaphyrins, are synthetic molecules designed to possess a variety of biological and chemical properties. These ring shaped molecules have a central core that is capable of binding various metal ions. The properties of these molecules may be modified by substitution of different metal ions into the central cavity. This approach enables us to synthesize a number of agents, each possessing unique properties. By making slight alterations of the chemical structure, we can produce an agent intended to perform a particular biologic function. Two lead product candidates have been produced and are being evaluated in clinical trials:

- **Xcytrin®** (moxetaxin gadolinium), is now in a pivotal randomized Phase 3 trial. It is a molecule designed to selectively localize in cancer cells and, by disrupting metabolism, induce cell death through a cellular process known as apoptosis. Xcytrin has the potential to be used for treating many types of cancer. Several Phase 1 and Phase 2 clinical trials are in progress evaluating Xcytrin as a stand alone agent, and in combination with chemotherapy, radiation therapy or biologic therapy with monoclonal antibodies. One of Xcytrin's chemical features allows it to be visualized in the body using standard magnetic resonance imaging (MRI) procedures. Using MRI, we have established that Xcytrin localizes selectively in cancers.
- **Antrin®** (moxetaxin lutetium), has completed Phase 1 clinical trials for the treatment of atherosclerosis involving the coronary arteries of the heart. Antrin targets the inflammatory cell component of a form of atherosclerosis known as vulnerable plaque, the leading cause of heart attacks. Using interventional cardiology procedures, Antrin is selectively activated at the diseased arterial site by light energy delivered into the blood vessel through an optical fiber.

Cellular metabolism is the biologic process through which cells produce energy necessary for their survival and synthesize simple building blocks into complex molecules necessary for life. Many diseased cells, including cancer cells and inflammatory cells in vulnerable plaque, have metabolic derangements that distinguish them from normal cells. Texaphyrins target these metabolic disturbances and accumulate at the disease site in minutes to a few hours after administration of the drugs. Texaphyrins can be cytotoxic to diseased cells, such as the case with Xcytrin, or they may be designed to be activated selectively at the site of disease, such as with light energy activation of Antrin. Texaphyrins are being developed to provide more selective therapy for diseases such as cancer and vulnerable plaque.

### Market Overview

#### *Cancer*

Cancer results from the uncontrolled multiplication of cells, which invade and interfere with the normal function of adjacent tissues and organs. Frequently, cancer cells become dislodged from their primary site and spread, or metastasize, to other places in the body. Approximately 1.2 million new cases of cancer are diagnosed annually in the United States. The appropriate cancer therapy for each patient depends on the cancer type and careful assessment of the size, location and existence of spread of the tumor using diagnostic imaging procedures. Therapy typically includes some combination of surgery, radiation therapy, chemotherapy or biologic therapy.

Most existing therapies of cancer tend to indiscriminately destroy both healthy and diseased cells and may cause serious side effects. As a result, substantial cancer research has been directed toward developing novel treatments that are more selective for the cancer and less toxic to normal tissues. These approaches seek to identify drugs, radiation therapy procedures or biologicals, which are capable of targeted destruction of the tumor with fewer side effects than existing treatments. Ideal agents would be those that are easy to deliver to the patient and capable of being used in combination with other cancer therapies to enhance efficacy without increasing toxicity to normal tissues. In addition to therapies intended to potentially cure patients, much of cancer therapy is utilized for palliation; it is given for reducing the pain and suffering from cancer. The following is a description of the market for current therapies used in the treatment of cancer:

- **Surgery.** Surgical removal of tumors is attempted whenever the tumor appears to be localized in a single, accessible site. Although potentially curative for localized cancers, many patients have disease that is inaccessible to complete surgical removal or has spread from the primary site. Spread of cancer from the primary site, known as

metastases, usually requires some form of systemic therapy with agents that distribute to all parts of the body.

- *Radiation Therapy.* Approximately 3,000 physicians specializing in radiation oncology administer radiation therapy to more than 700,000 patients annually in the United States. Radiation therapy is a localized treatment that may cure patients with tumors that are limited in size and have not spread from the primary site. Radiation therapy is frequently used to ameliorate the symptoms or signs of disease. This approach is not curative and is done to palliate or lessen patient suffering caused by tumor growth at a particular anatomic site. Radiation is usually applied to the tumor site several times per week over a period of two to six weeks. Radiation therapy often has toxic effects on healthy tissue surrounding the tumor because the radiation cannot be adequately targeted. An estimated 50% of newly diagnosed cancer patients, including those with cancers of the lung, breast, prostate, or head and neck region, will receive radiation therapy as part of their initial treatment. In addition, approximately 150,000 patients with persistent or recurrent cancer also will receive radiation therapy. A growing trend in radiation oncology is to deliver the radiation concomitantly with drugs in order to enhance radiation's effectiveness. Depending on the complexity and duration of treatment, a course of radiation therapy for cancer can cost between \$10,000 and \$25,000.
- *Chemotherapy.* More than 350,000 patients each year in the United States receive chemotherapy for treatment of many types of cancer. The serious or life-threatening side effects of chemotherapy agents, many of which are due to lack of selectivity, limit the effectiveness of this treatment. Chemotherapy drugs tend to distribute themselves throughout the body in normal tissues as well as in the tumor. Because of their toxicity to normal tissues, chemotherapy drugs can be administered only in small dosages and accordingly, the therapeutic benefits may be limited. Cancer cells also can become resistant to chemotherapy drugs, which has stimulated great interest in the identification of new agents with unique mechanisms of action.
- *Targeted Therapy.* Recently, monoclonal antibodies have been approved for the treatment of some cancers. Although more selective for certain cancers and usually safer than radiation and chemotherapy, these treatments are, so far, limited to only a few diseases such as cancers of the lymphoid system.

Most patients with cancer are treated with a combination of drugs or approaches that are intended to eradicate as much of the cancer as possible. The selection of agents is based on their mechanism of action and safety profile. The goal of combination therapy is to increase tumor destruction without causing unacceptable toxicity. Substantial research efforts are directed to finding new agents with novel mechanisms of action that can be added to existing combination therapy regimens.

#### *Atherosclerosis*

Atherosclerosis, or hardening of the arteries, is a disease in which cholesterol, other fatty materials and inflammatory cells are deposited in the walls of blood vessels, forming a build-up known as plaque. The accumulation of plaque narrows the interior of the blood vessels, reducing blood flow. Atherosclerosis in the coronary arteries can lead to heart attacks and death. In other blood vessels, atherosclerosis can lead to decreased mobility, loss of function, loss of limbs and other complications such as stroke. Atherosclerosis also can often result from the accumulation of inflammatory cells in the vessel wall. These diseased areas are vulnerable to mechanical stress and can acutely rupture causing a blood clot to form in the vessel. Recent evidence has established that most heart attacks are caused by rupture of a vulnerable plaque in the coronary arteries. New treatment approaches are needed to address this problem, which is believed to be responsible for over 80% of heart attacks.

Current treatments for atherosclerosis include coronary by-pass surgery and other techniques aimed at removing or relieving the plaque. Balloon angioplasty is a procedure using catheter devices inserted inside the vessels to mechanically compress or remove the obstruction. Currently, more than 600,000 patients per year in the United States undergo these procedures for treatment of atherosclerosis in the coronary arteries. These procedures require the use of anti-clotting drugs and, frequently, the use of devices known as stents inserted inside the vessels to reduce the incidence of re-closure, which results from traumatic damage to the vessel wall. Generally, these techniques have been limited to treating only focal areas or short sections of the diseased vessel. Vulnerable plaque remains an unmet medical need as balloon angioplasty and stents do not adequately address this condition.

## Our Business Strategy

The key elements of our business strategy include:

- *Focusing on proprietary drugs that address large markets for the treatment of cancer.* Although our versatile technology platform can be used to develop a wide range of pharmaceutical agents, we have focused our initial efforts in oncology where we have established strength in preclinical and clinical development and where accelerated regulatory approval and favorable pricing may be possible.
- *Evaluating Xcytrin in many types of cancer including its use as a single agent, in combination with radiation therapy and in combination with chemotherapy.* We are leveraging both our oncology experience and Xcytrin's versatility by conducting clinical trials in a variety of cancer types and clinical situations.
- *Creating diverse product opportunities based on our texaphyrin technology.* Our texaphyrin-based technology platform can be used to target many different types of disease. In addition to oncology, our research and development efforts are focused on developing new uses for texaphyrins to address unmet medical needs such as the treatment of vulnerable plaque.
- *Build oncology development capability and partner other product opportunities when adequate value in these products has been established.* We intend to establish strategic alliances for the development and commercialization of potential products that are outside the oncology area.

## Status of Products Under Development

The table below summarizes our product candidates and their stage of development:

Product	Disease Indication	Phase of Development (1)	Status
<b>CANCER THERAPY</b>			
XCYTRIN	Brain metastases from lung cancer	Phase 3	Enrolling (2)
	Primary brain tumor	Phase 2	Complete
	Advanced cancers	Phase 1 (three trials)	Enrolling
	Lymphoma	Phase 2	Enrolling
	Head and Neck Cancer	Phase 1	Enrolling
	Pancreatic cancer (3)	Phase 1	Enrolling
	Childhood gliomas (3)	Phase 1	Enrolling
	Lung cancer (3)	Phase 1	Enrolling
<b>ATHEROSCLEROSIS THERAPY</b>			
ANTRIN Phototherapy	Coronary artery disease	Phase 1	Complete

- (1) "Phase 1" means initial human clinical trials designed to establish the safety, dose tolerance and sometimes distribution of a compound. "Phase 2" means human clinical trials designed to establish safety, optimal dosage and preliminary activity of a compound. "Phase 3" means human clinical trials designed to lead to accumulation of data sufficient to support a new drug application, including substantial evidence of safety and efficacy.
- (2) One Phase 3 trial has been completed for brain metastases from a variety of cancers. See "Cancer Therapy – Clinical Status."
- (3) Studies conducted by the National Cancer Institute.

## Cancer Therapy with Xcytrin

Cancer cells have derangements in their metabolism, which distinguishes tumors from normal tissues. Many existing chemotherapy drugs are intended to exploit the metabolic abnormalities of cancer cells, which is the basis for mode of action of many of these drugs. Xcytrin's selective uptake in tumor cells occurs within minutes of administration and persists for hours, effectively concentrating the drug's effect in the tumor. The targeting of tumors is based on Xcytrin's novel mechanism of action. It reacts directly with various substances and growth factors, which are more abundant in cancer cells than in normal cells. These reactions inhibit the function of growth factors and produce by-products, which

weaken, or in some cases, kill the cancer cells. In laboratory studies, cancer cells incubated with Xcytrin undergo either growth arrest or apoptosis, a programmed sequence of events leading to cell death. The sensitivity of cancer cells to Xcytrin varies, depending on the type of cancer. Also in laboratory studies, Xcytrin enhances the activity of several commonly used chemotherapy agents and radiation. In published preclinical studies, animals receiving Xcytrin in combination with radiation therapy or chemotherapy had greater tumor response rates as compared to the control groups receiving equivalent doses of either radiation therapy or chemotherapy alone. Preclinical studies further indicate that Xcytrin increases the effect of radiation therapy at the tumor site, with no increased damage to surrounding healthy tissues. An additional feature of Xcytrin is that it is detectable by magnetic resonance imaging scanning (MRI), providing a method for monitoring its distribution in patients and for determining the precise size and location of tumors.

For our first product candidate, we intend to seek FDA approval of Xcytrin for treatment of patients receiving whole brain radiation therapy for non-small cell lung cancer that has spread to the brain. Patients with this problem, known as brain metastases, develop devastating complications, including severe headache, seizures, paralysis, blindness and impaired ability to think. Radiation therapy for treatment of this problem is performed on approximately 90,000 patients per year in the United States and is intended to prevent or reduce these complications. We believe that Xcytrin could eventually be used in many other tumor types and clinical situations requiring radiation therapy and chemotherapy.

*Clinical Status.* We have completed a Phase 1 clinical trial of Xcytrin in 38 adult patients with advanced cancer who received radiation therapy. This trial was designed to determine the toxicity of a single dose of the drug. Reversible kidney toxicity was found at the highest doses of drug tested. Accumulation of Xcytrin in lung cancer, breast cancer and other tumors has been confirmed using magnetic resonance imaging. The results of this study were published in the journal *Clinical Cancer Research* in 1999.

We have also completed an international multicenter Phase 1b/2 clinical trial in 61 patients to evaluate the safety and efficacy of Xcytrin in cancer patients receiving radiation therapy for treatment of tumors which had spread to the brain. Ten once-daily treatments were well tolerated. The maximally tolerated dose was 6.3 mg/kg. Dose limiting toxicity was found to be reversible elevation of liver function tests. The most common side effects were transient skin discoloration. Other adverse events occurring in at least ten percent of patients included nausea, vomiting, rash, headache and weakness. Xcytrin's tumor selectivity was established by MRI. The radiologic tumor response rate was 72% in the Phase 2 portion of the study. These results were published in 2001 in the *Journal of Clinical Oncology*. Although there was no control group in the study, the results suggested that Xcytrin increased tumor control in the brain beyond that expected with radiation alone.

Based on the results of our Phase 1b/2 trial, we conducted a randomized, controlled Phase 3 trial with Xcytrin for the treatment of patients with brain metastases (i.e. cancer that has spread to the brain from another part of the body) who were undergoing whole brain radiation therapy. The study was conducted at more than 50 leading cancer centers in the United States, Canada and Europe and enrolled 401 patients: 251 with lung cancer, 75 with breast cancer and 75 with other tumor types. The results of this study were published in July 2003 in the *Journal of Clinical Oncology*.

This study was designed to compare the safety and efficacy of standard whole brain radiation therapy (WBRT) to standard WBRT plus Xcytrin. The study had co-primary efficacy endpoints of survival and time to neurologic progression. Time to neurologic progression is a clinical benefit endpoint of special importance in patients with brain metastases since the majority of patients with brain metastases experience neurologic decline despite the use of WBRT. Physicians administer WBRT to patients with brain metastases primarily to prolong the time before the neurologic progression occurs. An independent events review committee (ERC), blinded to the treatment assignment, determined neurologic progression based on prespecified criteria. The trial design also included evaluation of neurologic progression determined by standardized investigator assessments.

The trial did not meet its primary endpoints for the entire patient population. However, there was a significant improvement in time to neurologic progression in the pre-specified stratum of lung cancer patients receiving Xcytrin. Over 60% of the patients on the study had lung cancer representing the largest sub-group of patients. Results from the events review committee and the investigators consistently showed that lung cancer patients receiving Xcytrin had a benefit in time to neurologic progression.

By investigator neurologic assessment, treatment with Xcytrin was associated with improved time to neurologic progression in the entire 401 patient population ( $P=0.018$ , unadjusted) with the benefit primarily confined to the lung cancer patients. These results were confirmed by the events review committee, which also found a benefit in the lung cancer population ( $P=0.048$ , unadjusted).

The majority of patients with brain metastases have extensive disease outside the brain and frequently die from causes unrelated to tumor growth in the brain. There was no significant difference in survival in patients who received Xcytrin (median 5.2 months) or who did not receive Xcytrin (median 4.9 months). We believe this lack of survival difference is due to death from tumor progression outside the brain, which would not be expected to be controlled by whole brain radiation therapy.

In our trial, patients with lung cancer differed substantially from patients with breast and other cancers. Lung cancer patients more often presented with brain metastases concomitantly with their initial primary tumor diagnosis, had brain as the only known site of metastases, had smaller tumor volume and less prior therapy. There are several possible reasons for the observed benefit in time to neurologic progression seen in the lung cancer sub-group. We believe that less extensive extracranial disease, more rapid and reversible development of central nervous system signs and symptoms and less exposure to prior neurotoxic chemotherapies provided a greater opportunity to demonstrate a clinical benefit in this group of patients. Similar results have been observed in other studies.

Neurocognitive function was one of the secondary endpoints of our study. Performance on neurocognitive tests is related to the patient's ability to manage finances, recognize safe and unsafe behaviors, and remember and comply with medication regimens. Consistent with the results of the ERC and investigator time to neurologic progression, neurocognitive testing revealed a benefit in prolonging time to neurocognitive progression in six tests of memory and executive function for lung cancer patients treated with Xcytrin.

The administration of Xcytrin was well tolerated with 96% of the intended doses delivered during the trial. Serious drug related adverse events that were noted include hypertension (5.8%), asthenia (2.6%), hyponatremia (2.1%), leukopenia (2.1%), hyperglycemia (1.6%) and vomiting (1.6%).

Based on the clinical activity seen in our Phase 3 trial in patients with brain metastases from lung cancer, we have begun a pivotal Phase 3 clinical trial to confirm the potential clinical benefits observed in patients with brain metastases from non-small cell lung cancer, known as the SMART (Study of Neurologic Progression with Motexafin Gadolinium And Radiation Therapy) trial. We plan to enroll 550 patients in this international, randomized controlled trial. We plan to complete enrollment in this trial in the fourth calendar quarter of 2004. Patients will be randomized to receive either Xcytrin plus WBRT or WBRT alone. A battery of neurologic and neurocognitive assessments will be made with the goal of establishing that the function of the brain is improved with Xcytrin. Time to neurologic progression, the primary study endpoint, will be determined by a blinded events review committee. Secondary endpoints of this trial will include survival, neurocognitive function and time to loss of functional independence.

We requested and received a Special Protocol Assessment from the FDA for the SMART trial. Special Protocol Assessment provides for sponsors of clinical trials to receive official FDA evaluation, guidance and agreement on pivotal trials that will form the basis for final approval.

The FDA has indicated that our Phase 3 trial's primary endpoint of time to neurologic progression is an endpoint that can provide the basis for approval of the drug. This trial is now open at more than 90 centers in the U.S., Europe and Australia.

We have also completed patient enrollment in a multicenter Phase 2 trial with Xcytrin and radiation for the treatment of glioblastoma multiforme, a malignant primary brain tumor. In addition to our studies using Xcytrin in combination with radiation, the National Cancer Institute is sponsoring several clinical trials with Xcytrin and radiation for additional cancer types including primary brain tumors, pediatric brain tumors, lung cancer and pancreatic cancer.

Our strategy is to evaluate Xcytrin for the treatment of a diverse range of cancer types and in various clinical situations including Xcytrin as a single agent and in combination with chemotherapy and/or radiation therapy. We have begun Phase 2 clinical trials with Xcytrin used alone in hematologic cancers such as lymphomas. Phase 1 trials are underway evaluating Xcytrin given in combination with doxorubicin and with docetaxel (Taxotere®) for lung, prostate, ovarian and breast cancer. We expect interim results from an ongoing Phase 1 trial with Xcytrin combined with radiation and chemotherapy for the treatment of newly diagnosed, advanced head and neck cancer patients to be presented at a major medical conference in late 2003.

## Atherosclerosis Therapy

### *Antrin Phototherapy of Vulnerable Plaque*

Preclinical studies conducted by Pharmacyclics and our collaborators have demonstrated that texaphyrins accumulate in vascular plaque caused by atherosclerosis. Preclinical studies have indicated that following intravenous injection of Antrin, light delivered into the blood vessel using an optical fiber resulted in non-mechanical reduction or elimination of the plaque without damage to the lining of the vessel. These studies have shown that Antrin and other texaphyrins accumulate in the inflammatory cells within atherosclerosis and that following phototherapy the number of these cells is reduced. We believe that these results suggest that Antrin Phototherapy has the potential to eliminate or reduce plaque without complications such as thrombosis and reclosure. Additional preclinical studies further indicated that Antrin Phototherapy could be used to treat longer segments of blood vessels, which is not possible with other currently available techniques. Vulnerable plaque is rich in inflammatory cells and prone to rupture causing a sudden blood clot and closure of the vessel. It is now believed that the majority of heart attacks are caused by rupture of vulnerable plaque, which is frequently present in multiple locations throughout the coronary arteries. Removal of inflammatory cells suggests that Antrin may reduce or stabilize vulnerable plaque and this may be achievable over long segments of the coronary arteries.

*Clinical Status.* Our Phase 1 clinical trial with Antrin Phototherapy for the treatment of coronary artery disease in 79 patients receiving balloon angioplasty and stents was published in the September 2003 issue of the journal *Circulation*. This study was primarily designed to evaluate the safety of various doses of drug and light. Patients received follow-up angiograms six months after treatment to evaluate effects of the treatment on the blood vessels. No major treatment-related angiographic or biochemical adverse effects or abnormalities were observed and no dose-limiting toxicities were noted. No instances of emergency coronary artery bypass, death, stroke or myocardial infarction occurred in patients who received both Antrin infusion and endovascular illumination and activation of the drug. The most frequently reported side effects were mild, transient rash and reversible mild tingling in the hands and feet, some of which lasted days to weeks, but did not require clinical intervention. Optimum drug and light doses were identified for use in subsequent clinical trials.

We believe that Antrin phototherapy may be useful in the treatment or stabilization of vulnerable plaque. We currently plan to establish a corporate alliance for Antrin before performing any additional clinical development.

### **Research, Clinical Development and Marketing Collaborations**

We rely on relationships with third parties to expand certain research, clinical development, process development, manufacturing, and sales and marketing functions. In the photodynamic therapy field, we have used outside collaborations for development of light sources and delivery devices for use in our preclinical studies and clinical trials with Antrin.

*National Cancer Institute Collaboration.* In April 1997, the Decision Network Committee of the National Cancer Institute's Division of Cancer Treatment, Diagnosis and Centers voted unanimously to sponsor and fund clinical development of Xcytrin as a radiation enhancer for cancer treatment. Under this cooperative research and development agreement, Pharmacyclics and the National Cancer Institute jointly select clinical trials which will be conducted at leading medical centers for various types of cancer. The National Cancer Institute is conducting several separate clinical trials for treatment of brain tumors and cancers involving the lung and pancreas. We believe that these National Cancer Institute-sponsored trials will supplement our own clinical development efforts for Xcytrin. Although third parties will be conducting the trials, we will provide clinical supplies of our drugs and we intend to monitor the progression and results of these trials.

*The University of Texas Agreements.* We collaborate with and sponsor research and development programs at The University of Texas at Austin, through a group headed by Jonathan Sessler, Ph.D., Professor of Chemistry at The University of Texas at Austin. Such collaborations and programs extend our research capabilities in the field of expanded porphyrin chemistry. We have entered into two license agreements with The University of Texas at Austin that grant us the worldwide, exclusive right to patents or patent applications that relate to or result from research conducted at The University of Texas at Austin on the use, development and syntheses of expanded porphyrin molecules, and research conducted at The University of Texas at Dallas on the incorporation of paramagnetic metals into zeolites for use as MRI contrast agents. These agreements require us to pay royalties as a percentage of net sales to The University of Texas for products incorporating the licensed technology, including each of our current product candidates. In addition, we and

The University of Texas at Austin have entered into sponsored research agreements which expand the products, inventions and discoveries developed by The University of Texas at Austin to which our license rights apply.

### **Patents and Proprietary Technology**

We believe our success depends upon our ability to protect our proprietary technology. We, therefore, aggressively pursue, prosecute, protect and defend patent applications, issued patents, trade secrets, and licensed patent and trade secret rights covering certain aspects of our technology.

Our patents, patent applications, and licensed patent rights cover various compounds, pharmaceutical formulations and methods of use. We own or have license rights to:

- 71 issued U.S. patents; and
- 15 other pending U.S. patent applications.

The issued U.S. patents expire between 2009 and 2019. We also own or license 196 issued non-U.S. patents including 154 patents issued throughout Europe and 85 pending non-U.S. patent applications filed regionally under the Patent Cooperation Treaty and with the European Patent Office, and nationally in Canada, Japan, Australia and certain other countries.

We may be unsuccessful in prosecuting our patent applications or patents may not issue from our patent applications. Even if patents are issued and maintained, these patents may not be of adequate scope to benefit us, or may be held invalid and unenforceable against third parties.

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We require all of our employees, consultants, advisors and the like to execute appropriate confidentiality and assignment-of-inventions agreements. These agreements typically provide that all materials and confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties; except in specific circumstances, and that all inventions arising out of the relationship with Pharmacyclics shall be our exclusive property.

### **Drug and Device Supply Agreements**

We currently use third parties to manufacture various components of our products under development.

*Texaphyrin-based Products.* We have entered into commercial supply agreements with three manufacturers who each manufacture a separate component related to the complete manufacturing of our Xcytrin drug substance. In fiscal 2001, we took delivery of commercial quantities of Xcytrin drug substance. We have also entered into a commercial supply agreement for the formulation, filling, packaging and labeling of commercial quantities of Xcytrin. We utilize the same contract manufacturer for the formulation, filling, packaging and labeling of clinical quantities of Xcytrin and Antrin.

*Light Production and Delivery Devices.* In connection with our development of Antrin phototherapy, we have developed certain light sources and delivery methods, such as lasers and fiber optic devices. We have purchased laser devices capable of producing the required wavelength of light for use with Antrin phototherapy. We have acquired, from a contract supplier, cylindrically diffusing light fibers for animal studies and for use in our Antrin clinical trials. In addition, we may seek other suppliers of light delivery devices for clinical trials and commercial purposes, although we cannot be certain that any agreements will be reached with such suppliers on terms commercially reasonable to us, if at all.

### **Competition**

We face intense competition from pharmaceutical companies, universities, governmental entities and others in the development of therapeutic and diagnostic agents for the treatment of diseases which we target.

Although the FDA has not yet approved any agents for the treatment of brain metastases, we expect significant competition in this field, as we believe that one or more companies, such as Allos Therapeutics, Inc., are developing and testing products which may compete directly with our Xcytrin product under development. Allos' product was tested in a Phase 3 trial and appeared to improve survival in a subset of patients with brain metastases from breast cancer, although the trial's primary endpoints were not met. These companies may succeed in developing technologies and products that are more effective than ours or would render our products or technologies obsolete. Moreover, certain existing

chemotherapy agents also are used as radiation enhancers. See "Risk Factors — We face rapid technological change and intense competition."

We also face intense competition in the treatment of atherosclerosis, which currently includes the use of pharmaceutical agents and devices. Various drugs also have been shown to reduce or prevent atherosclerosis. Balloon angioplasty and stents are widely used and generally accepted techniques to reduce the narrowing of vessels by atherosclerosis. Recently, drug eluting stents have been approved for use in preventing re-stenosis following balloon angioplasty. No agents or devices have been approved for treatment of vulnerable plaque.

### **Government Regulation and Product Approval Process**

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our products. We believe that our products will be regulated as drugs or as a combination of drug and device, by the FDA rather than as biologics or solely devices.

The process required by the FDA before our products may be marketed in the U.S. generally involves the following:

- preclinical laboratory and animal tests;
- submission of an Investigational New Drug (IND) application, which must become effective before clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed pharmaceutical in our intended use; and
- FDA approval of a new drug application.

The testing and approval process requires substantial time, effort, and financial resources; and we cannot be certain that any approval will be granted on a timely basis, if at all.

Preclinical tests include laboratory evaluation of the product, its chemistry, formulation and stability, as well as animal studies to assess the potential safety and efficacy of the product. We then submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of an IND, which must become effective before we may begin human clinical trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. Our submission of an IND may not result in FDA authorization to commence clinical trials. Further, an independent Institutional Review Board at the medical center proposing to conduct the clinical trials must review and approve any clinical study.

Human clinical trials are typically conducted in three sequential phases which may overlap:

- **Phase 1:** The drug is initially introduced into healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.
- **Phase 2:** Involves studies in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- **Phase 3:** When Phase 2 evaluations demonstrate that a dosage range of the product is effective and has an acceptable safety profile, Phase 3 trials are undertaken to further evaluate dosage, clinical efficacy and to further test for safety in an expanded patient population at geographically dispersed clinical study sites.

In the case of products for severe or life-threatening diseases such as cancer, the initial human testing is often conducted in patients rather than in healthy volunteers. Since these patients already have the target disease, these studies may provide initial evidence of efficacy traditionally obtained in Phase 2 trials and thus these trials are frequently referred to as Phase 1/2 trials. We cannot be certain that we will successfully complete Phase 1, Phase 2 or Phase 3 testing of our product candidates within any specific time period, if at all. Furthermore, the FDA, the relevant Institutional



Review Board or the sponsor may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The results of product development, preclinical studies and clinical studies are submitted to the FDA as part of a new drug application, or NDA, for approval of the marketing and commercial shipment of the product. The FDA may not file the NDA for review if the applicable regulatory criteria are not satisfied or may require additional clinical data. Even if such data is accepted for filing, the FDA may ultimately decide that the new drug application does not satisfy the criteria for approval. Once issued, the FDA may withdraw product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products which have been commercialized, and the agency has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

On November 21, 1997, President Clinton signed into law the Food and Drug Administration Modernization Act. That act codified the FDA's policy of granting "Fast Track" approval for cancer therapies and other therapies intended to treat severe or life-threatening diseases. Previously, the FDA approved cancer therapies primarily based on patient survival rates and/or data on improved quality of life. The FDA considered evidence of partial tumor shrinkage, while often part of the data relied on for approval, insufficient by itself to warrant approval of a cancer therapy, except in limited situations. Under the FDA's new policy, which became effective on February 19, 1998, the FDA has broadened authority to consider evidence of partial tumor shrinkage or other clinical outcomes for approval. This new policy is intended to facilitate the study of cancer therapies and shorten the total time for marketing approvals.

In addition to the drug approval requirements applicable to our Antrin product for phototherapy of atherosclerosis, we will also need to obtain FDA approval for the laser and associated light delivery devices used in such treatments. To obtain approval of such devices, Pharmacyclics and the manufacturers of such devices must submit additional clinical data obtained from the use of such devices with Antrin, which may further delay or hinder the approval process for these photosensitizers. Manufacturers of such light delivery devices currently are under no obligation to us to file or pursue such applications, and any delay or refusal on their part to do so could have a material adverse effect on us.

Satisfaction of the above FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and the actual time required may vary substantially, based upon the type, complexity and novelty of the pharmaceutical product. Government regulation may delay or prevent marketing of potential products for a considerable period of time and to impose costly procedures upon our activities. We cannot be certain that the FDA or any other regulatory agency will grant approval for any of our products under development on a timely basis, if at all. Success in preclinical or early stage clinical trials does not assure success in later stage clinical trials. Data obtained from preclinical and clinical activities is not always conclusive and may be susceptible to varying interpretations which could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be significantly limited to specific indications. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delays in obtaining, or failures to obtain regulatory approvals would have a material adverse effect on our business. Marketing our products abroad will require similar regulatory approvals and is subject to similar risks. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

Any products manufactured or distributed by us pursuant to FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with good manufacturing practices, which impose certain procedural and documentation requirements upon us and our third party manufacturers. We cannot be certain that we or our present or future suppliers will be able to comply with the GMP regulations and other FDA regulatory requirements.

The FDA regulates drug labeling and promotion activities. The FDA has actively enforced regulations prohibiting the marketing of products for unapproved uses. Under the Modernization Act of 1997, the FDA will permit the promotion of a drug for an unapproved use in certain circumstances, but subject to very stringent requirements. We and our products are also subject to a variety of state laws and regulations in those states or localities where our products are or will be marketed. Any applicable state or local regulations may hinder our ability to market our products in those states or localities. We are also subject to numerous federal, state and local laws relating to such matters as safe working con-

ditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

The FDA's policies may change and additional government regulations may be enacted which could prevent or delay regulatory approval of our potential products. Moreover, increased attention to the containment of health care costs in the U.S. and in foreign markets could result in new government regulations which could have a material adverse effect on our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation which might arise from future legislative or administrative action, either in the U.S. or abroad.

### **Employees**

As of June 30, 2003, we had 112 employees, 3 of whom were part-time. Eighty-nine of our employees are engaged in research, development, preclinical and clinical testing, manufacturing, quality assurance and quality control and regulatory affairs and 24 in marketing, finance, administration and operations. Twenty-two of our employees have an M.D. or Ph.D. degree. Our future performance depends in significant part upon the continued service of our key scientific, technical and senior management personnel, none of whom is bound by an employment agreement requiring service for any defined period of time. The loss of the services of one or more of our key employees could harm our business. None of our employees are represented by a labor union. We consider our relations with our employees to be good.

## Important Factors Regarding Forward-Looking Statements

*This report contains forward-looking statements. These statements relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "possible," "potential," "predict," "should" or "will" or the negative of such terms or other comparable terminology. In particular, forward-looking statements include:*

- *information concerning possible or assumed future results of operations, trends in financial results and business plans;*
- *statements about our product development schedule;*
- *statements about our expectations for regulatory approvals for any of our product candidates;*
- *statements about the level of our costs and operating expenses;*
- *statements about our future capital requirements and the sufficiency of our cash, cash equivalents, investments and other financing proceeds to meet these requirements;*
- *other statements about our plans, objectives, expectations and intentions; and*
- *other statements that are not historical fact.*

*From time to time, we also may provide oral or written forward-looking statements in other materials we release to the public. Forward-looking statements are only predictions that provide our current expectations or forecasts of future events. Any or all of our forward-looking statements in this report and in any other public statements are subject to unknown risks, uncertainties and other factors may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, performance or achievements. You should not place undue reliance on these forward-looking statements.*

*We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosures we make on related subjects in our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. Also note that we provide a cautionary discussion of risks, uncertainties and possibly inaccurate assumptions relevant to our business under the caption Risk Factors in this report. These are risks that we think could cause our actual results to differ materially from expected or historical results.*

## FACTORS THAT MAY AFFECT FUTURE OPERATING RESULTS

### *Risks Related to Pharmacocyclics*

We operate in an environment that involves a number of risks and uncertainties. The risks and uncertainties described below are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. If any of the following risks actually occur, our business, results of operations and financial condition would suffer. The risks discussed below also include forward-looking statements, and our actual results may differ substantially from those discussed in these forward-looking statements.

### **All of our product candidates are in development, and we cannot be certain that any of our products under development will be commercialized**

To be profitable, we must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute our products under development. The time frame necessary to achieve these goals for any individual product is long and uncertain. Before we can sell any of our products under development, we must demonstrate through preclinical (animal) studies and clinical (human) trials that each product is safe and effective for human use for each targeted disease. We have conducted and plan to continue extensive and costly clinical trials to assess the safety and effectiveness of our potential products. We cannot be certain that we will be permitted to begin or continue our planned clinical trials for our potential products, or if permitted, that our potential products will prove to be safe and produce their intended effects.

The completion rate of our clinical trials depends upon, among other factors, the rate of patient enrollment. We may fail to obtain adequate levels of patient enrollment in our clinical trials. Delays in planned patient enrollment may result in increased costs, delays or termination of clinical trials, which could have a material adverse effect on us.

Additionally, demands on our clinical staff have been increasing and we expect they will continue to increase due to our monitoring of additional large-scale clinical trials. We may fail to effectively oversee and monitor these many simultaneous clinical trials, which would result in increased costs or delays of our clinical trials. Even if these clinical trials are completed, we may fail to complete and submit a new drug application as scheduled for many reasons, including, as is the case with our first Phase 3 trial of Xcytrin, failure to meet our primary endpoints. Even if we are able to submit a new drug application, the Food and Drug Administration may refuse to file our application or may not approve our application in a timely manner or at all.

Data already obtained from preclinical studies and clinical trials of our products under development do not necessarily predict the results that will be obtained from later preclinical studies and clinical trials. Moreover, data from clinical trials we are conducting is susceptible to varying interpretations which could delay, limit or prevent regulatory approval. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. The failure to adequately demonstrate the safety and effectiveness of a product under development could delay or prevent regulatory clearance of the potential product and would materially harm our business. Our clinical trials may not demonstrate the sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approval or may not result in marketable products. In this regard, our initial Phase 3 trial of Xcytrin failed to meet its co-primary endpoints even though our Phase 1b/2 trial showed a benefit for treated patients. The outcome of the current Phase 3 trial may delay or prevent the regulatory clearance of Xcytrin as a treatment for brain metastases in patients with lung cancer and may result in material harm to our business.

#### **We have a history of operating losses and we expect to continue to have losses in the future**

We have incurred significant operating losses since our inception in 1991 and, as of June 30, 2003, had an accumulated deficit of approximately \$186.6 million. We expect to continue to incur substantial additional operating losses until the commercialization of our products generates sufficient revenues to cover our expenses. Our achieving profitability depends upon our ability, alone or with others, to successfully complete the development of our products under development, and obtain required regulatory clearances and successfully manufacture and market our proposed products. Our lead product, Xcytrin, currently being developed for the potential treatment of brain metastases originating from non-small cell lung cancer, may receive regulatory clearance on a delayed basis or may not receive such clearance at all, which would have a material impact on our ability to become profitable. To date, we have not generated revenue from the commercial sale of our products.

#### **Failure to obtain product approvals or comply with ongoing governmental regulations could adversely affect our business**

The manufacture and marketing of our products and our research and development activities are subject to extensive regulation for safety, efficacy and quality by numerous government authorities in the United States and abroad. Before receiving U.S. Food and Drug Administration (FDA) clearance to market a product, we will have to demonstrate that the product is safe and effective on the patient population and for the diseases that will be treated. Clinical trials, and the manufacturing and marketing of products, are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities. The Federal Food, Drug and Cosmetic Act and other federal, state and foreign statutes and regulations govern and influence the testing, manufacture, labeling, advertising, distribution and promotion of drugs and medical devices. As a result, clinical trials and regulatory approval can take a number of years to accomplish and require the expenditure of substantial resources. Data obtained from clinical trials are susceptible to varying interpretations which could delay, limit or prevent regulatory clearances. Data from our completed initial Phase 3 clinical trial of Xcytrin was not sufficient to obtain regulatory clearance. Any approval of Xcytrin will require at least an additional clinical trial. Conducting additional large-scale trials will cause significant delays in approval and consume additional resources and may not be sufficient to obtain regulatory clearance.

In addition, we may encounter delays or rejections based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. We may encounter similar delays in foreign countries. We may be unable to obtain requisite

approvals from the FDA and foreign regulatory authorities and even if obtained, such approvals may not be on a timely basis, or they may not cover the clinical uses that we specify.

Furthermore, clearance may entail ongoing requirements for post-marketing studies. The manufacture and marketing of drugs are subject to continuing FDA and foreign regulatory review and later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions, including withdrawal of the product from the market. Any of the following events, if they were to occur, could delay or preclude us from further developing, marketing or realizing full commercial use of our products, which in turn would have a material adverse effect on our business, financial condition and results of operations:

- failure to obtain and thereafter maintain requisite governmental approvals;
- failure to obtain approvals for specific indications of our products under development; or
- identification of serious and unanticipated adverse side effects in our products under development.

Manufacturers of drugs also must comply with the applicable FDA Good Manufacturing Practice regulations, which include quality control and quality assurance requirements as well as the corresponding maintenance of records and documentation. Manufacturing facilities are subject to ongoing periodic inspection by the FDA and corresponding state agencies, including unannounced inspections, and must be licensed before they can be used in commercial manufacturing of our products. We or our present or future suppliers may be unable to comply with the applicable Good Manufacturing Practice regulations and other FDA regulatory requirements. We have not been subject to a Good Manufacturing Practice inspection by the FDA or any state agency. We may be subject to delays in commercializing our products for Antrin phototherapy due to delays in approvals of the third-party light sources required for this product.

**Acceptance of our products in the marketplace is uncertain, and failure to achieve market acceptance will harm our business**

Even if approved for marketing, our products may not achieve market acceptance. The degree of market acceptance will depend upon a number of factors, including:

- the receipt of regulatory approvals for the indications that we are studying;
- the establishment and demonstration in the medical community of the safety and clinical efficacy of our products and their potential advantages over existing therapeutic products and diagnostic and/or imaging techniques; and
- pricing and reimbursement policies of government and third-party payors such as insurance companies, health maintenance organizations and other plan administrators.

Physicians, patients, payors or the medical community in general may be unwilling to accept, utilize or recommend any of our products.

**We may fail to adequately protect or enforce our intellectual property rights or secure rights to third-party patents**

A number of third-party patent applications have been published, and some have issued, relating to biometallic and expanded porphyrin chemistries. It is likely that competitors and other third parties have and will continue to file applications for and receive patents relating to similar or even the same compositions, methods or designs as those of our products. If any third-party patent claims are asserted against the company's products and are upheld as valid and infringed by our products, we could be prevented from practicing the subject matter claimed in such patents, require license(s) or have to redesign our products or processes to avoid infringement. Such licenses may not be available or, if available, may not be on terms acceptable to us. Alternatively, we may be unsuccessful in any attempt to redesign our products or processes to avoid infringement. Litigation or other legal proceedings may be necessary to defend against claims of infringement, to enforce our patents, or to protect our trade secrets, and could result in substantial cost to the company and diversion of our efforts.

We are aware of several U.S. patents owned or licensed by Schering AG that relate to pharmaceutical formulations and methods for enhancing magnetic resonance imaging. We have obtained the opinion of outside patent counsel that our magnetic resonance imaging detectable compounds do not infringe the claims of such patents. Nevertheless, Schering AG may still choose to assert one or more of those patents. If any of our products were legally determined to be infringing a valid and enforceable claim of any of Schering AG's patents, our business could be materially adverse-

ly affected. Further, any allegation by Schering AG that we infringed their patents would likely result in significant legal costs and require the diversion of substantial management resources. We are aware that Schering AG has asserted patent rights against at least one other company in the contrast agent imaging market and that a number of companies have entered into licensing arrangements with Schering AG with respect to one or more of such patents. We cannot be certain that we would be successful in defending a lawsuit or able to obtain a license on commercially reasonable terms from Schering AG, if required.

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We require our employees, consultants, advisors and the like to execute appropriate confidentiality and assignment-of-inventions agreements with us. These agreements typically provide that all materials and confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties, except in specific circumstances, and that all inventions arising out of the relationship with Pharmacyclics shall be our exclusive property. These agreements may be breached, and in some instances, we may not have an appropriate remedy available for breach of the agreements. Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer our information and techniques, or otherwise gain access to our proprietary technology. We may be unable to meaningfully protect our rights in unpatented proprietary technology.

### **We rely heavily on third parties**

We currently depend heavily and will depend heavily in the future on third parties for support in product development, clinical development, manufacturing, marketing and distribution of our products. We rely on contract clinical research organizations (CROs) for various aspects of our clinical development activities including clinical trial monitoring, data collection and data management. Any failure of such CROs to successfully accomplish these activities could have a material adverse effect on our ability to complete clinical development of our products.

We have no expertise in the development of light sources and associated light delivery devices required for our Antrin phototherapy product under development. Successful development, manufacturing, approval and distribution of this product will require third party participation for the required light sources, associated light delivery devices and other equipment. Failure to develop such relationships may require us to develop additional supply sources which may require additional clinical trials and regulatory approvals and could materially delay commercialization of our Antrin product under development. We may be unable to establish or maintain relationships with other supply sources on a commercially reasonable basis, if at all, or alternatively, the enabling devices may not receive regulatory approval.

### **We have limited manufacturing experience and thus rely heavily upon contract manufacturers**

We have no manufacturing facilities and we currently rely on third parties for manufacturing and storage activities related to all of our products in development. Our manufacturing strategy presents the following risks:

- delays in scale-up to quantities needed for multiple clinical trials or failure to manufacture such quantities to our specifications, or deliver such quantities on the dates we require, could cause delay or suspend clinical trials, regulatory submissions and commercialization of our products in development;
- our current and future manufacturers are subject to on-going periodic unannounced inspections by the FDA and corresponding regulatory agencies for compliance with strictly enforced Good Manufacturing Practices and similar foreign standards;
- if we need to change to other commercial manufacturing contractors, the FDA and comparable foreign regulators must approve material manufactured by these contractors prior to our use. This would require new testing and compliance inspections. The new manufacturers would have to practice substantially equivalent processes for the production of our products; and
- when necessary, our current manufacturers might not be able to fulfill our commercial needs, which would require us to seek new manufacturing arrangements and may result in substantial delays in meeting market demand.

Any of these factors could delay clinical trials or commercialization of our products under development and entail higher costs.

### **We lack marketing and sales experience**

We currently have limited marketing, sales and distribution experience. We must develop a sales force with technical expertise. We have no experience in developing, training or managing a sales force. We will incur substantial additional expenses in developing, training and managing such an organization. We may be unable to build such a sales force, the cost of establishing such a sales force may exceed any product revenues, or our direct marketing and sales efforts may be unsuccessful. In addition, we compete with many other companies that currently have extensive and well-funded marketing and sales operations. Our marketing and sales efforts may be unable to compete successfully against those of such other companies.

### **Our capital requirements are uncertain and we may have difficulty raising needed capital in the future**

We have expended and will continue to expend substantial funds to complete the research, development and clinical testing of our products. We will expend additional funds for these purposes, to establish additional clinical and commercial-scale manufacturing arrangements and to provide for the marketing and distribution of our products. In this regard, we may require additional funds to complete our current Phase 3 trial with Xcytrin for the potential treatment of brain metastases in lung cancer patients.

Additional funds may not be available on acceptable terms, if at all. If adequate funds are unavailable from operations or additional sources of financing, we may have to delay, reduce the scope of or eliminate one or more of our research or development programs which would materially and adversely affect our business, financial condition and operations.

We believe that our cash, cash equivalents and investments, will be adequate to satisfy our capital needs through at least fiscal year 2005. As described in Item 7., Management's Discussion and Analysis of Financial Condition and Results of Operations, this is a forward-looking statement and is subject to risks and uncertainties. Our actual capital requirements will depend on many factors, including:

- continued progress of our research and development programs;
- our ability to establish collaborative arrangements;
- progress with preclinical studies and clinical trials;
- the time and costs involved in obtaining regulatory clearance;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- competing technological and market developments; and
- our ability to market and distribute our products and establish new licensing arrangements.

We may seek to raise any necessary additional funds through equity or debt financings, collaborative arrangements with corporate partners or other sources which may be dilutive to existing stockholders or subject us to restrictive covenants. In addition, in the event that additional funds are obtained through arrangements with collaborative partners or other sources, such arrangements may require us to relinquish rights to some of our technologies, product candidates or products under development that we would otherwise seek to develop or commercialize ourselves.

### *Risks Related to Our Industry*

#### **We face rapid technological change and intense competition**

The pharmaceutical industry is subject to rapid and substantial technological change. Developments by others may render our products under development or technologies noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition in the industry from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase. Many of these entities have significantly greater research and development capabilities than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors' financial, marketing, manufacturing and other resources.

We are a relatively new enterprise and are engaged in the development of novel therapeutic technologies. As a result, our resources are limited and we may experience technical challenges inherent in such novel technologies.

Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products. Some of these products may have an entirely different approach or means of accomplishing similar therapeutic effects than our products. Our competitors may develop products that are safer, more effective or less costly than our products and, therefore, present a serious competitive threat to our product offerings.

The widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our products even if commercialized. The diseases for which we are developing our therapeutic products can also be treated, in the case of cancer, by surgery, radiation and chemotherapy, and in the case of atherosclerosis, by surgery, angioplasty, drug therapy and the use of devices to maintain and open blood vessels. These treatments are widely accepted in the medical community and have a long history of use. The established use of these competitive products may limit the potential for our products to receive widespread acceptance if commercialized.

#### **The price of our common stock may be volatile**

The market prices for securities of small capitalization biotechnology companies, including ours, have historically been highly volatile. The market has from time to time experienced significant price and volume fluctuations unrelated to the operating performance of particular companies. The market price of our common stock may fluctuate significantly due to a variety of factors, including:

- the results of preclinical testing and clinical trials by us or our competitors;
- technological innovations or new therapeutic products;
- governmental regulation;
- developments in patent or other proprietary rights;
- litigation;
- public concern as to the safety of products developed by us or others;
- comments by securities analysts; and
- general market conditions in our industry.

In addition, if any of the risks described in these "Risk Factors" actually occurred, it could have a dramatic and material adverse impact on the market price of our common stock.

#### **We are subject to uncertainties regarding health care reimbursement and reform**

The continuing efforts of government and insurance companies, health maintenance organizations and other payors of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the availability of capital. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could have a material adverse effect on our business, financial condition and results of operations.

Our ability to commercialize our products successfully will depend in part on the extent to which appropriate reimbursement levels for the cost of our products and related treatment are obtained from governmental authorities, private health insurers and other organizations, such as HMOs. Third-party payors are increasingly challenging the prices charged for medical products and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for or rejection of our products. The cost containment measures that health care payors and providers are instituting and the effect of any health care reform could materially adversely affect our ability to operate profitably.



### **Our business exposes us to product liability claims**

The testing, manufacture, marketing and sale of our products involve an inherent risk that product liability claims will be asserted against us. Although we are insured against such risks in connection with clinical trials and commercial sales of our products, our present product liability insurance may be inadequate. A successful product liability claim in excess of our insurance coverage could have a material adverse effect on our business, financial condition and results of operations. Any successful product liability claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable or reasonable terms. In addition, product liability coverage may cease to be available in sufficient amounts or at an acceptable cost. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our pharmaceutical products. A product liability claim or recall would have a material adverse effect on our reputation, business, financial condition and results of operations.

### **Our business involves environmental risks**

In connection with our research and development activities and our manufacture of materials and products, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development involves the controlled use of hazardous materials, including but not limited to certain hazardous chemicals and radioactive materials. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an occurrence, we could be held liable for any damages that result and any such liability could exceed our resources.

## Executive Officers and Directors

Executive officers and directors of the company, and their ages as of August 31, 2003, are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Richard A. Miller, M.D. ....	52	President, Chief Executive Officer and Director
Timothy G. Whitten ....	46	Senior Vice President, Commercial Operations
Leiv Lea ....	49	Vice President, Finance and Administration and Chief Financial Officer and Secretary
Hugo Madden, Ph.D. ....	54	Vice President, Chemical Operations
See-Chun Phan, M.D. ....	39	Vice President, Clinical Research
Markus F. Renschler, M.D. ....	42	Vice President, Oncology Clinical Development
Miles R. Gilburne (2)(3) ....	52	Director
Loretta M. Itri, M.D. (2)(3) ....	54	Director
Richard M. Levy, Ph.D. (1)(3) ....	65	Director
William R. Rohn (1)(3) ....	60	Director
Craig C. Taylor (2)(3) ....	53	Director

- (1) Member of Compensation Committee.
- (2) Member of Audit Committee.
- (3) Member of Nominating and Corporate Governance Committee.

*Dr. Miller* has served as President, Chief Executive Officer and a Director since he co-founded the company in April 1991. Dr. Miller was a co-founder of IDEC Pharmaceuticals Corporation and from 1984 to February 1992 served as Vice President and a Director. Dr. Miller also is a Clinical Professor of Medicine (Oncology) at Stanford University Medical Center. Dr. Miller received his M.D. from the State University of New York Medical School and is board certified in both Internal Medicine and Medical Oncology.

*Mr. Whitten* has served as Senior Vice President, Commercial Operations since September 2001. From 1985 through 2001, Mr. Whitten served in a variety of positions at Bristol-Myers Squibb, most recently as: Vice President, Global Marketing, Oncology, from February 2000 to September 2001; Vice President Global Marketing, Oncology and Immunology from February 1999 to February 2000; Vice President, Pravastatin Initiative, from November 1997 to February 1999; Vice President, Marketing, Oncology and Immunology for the U.S. Business Unit, from April 1996 to October 1997. Mr. Whitten received his B.S. in Pharmacy from West Virginia University and an M.B.A. from the University of Virginia.

*Mr. Lea* has served as Vice President, Finance and Administration and Chief Financial Officer since December 1998 and Secretary since June 2003. Prior to that, Mr. Lea served as Vice President, Finance and Administration from December 1997 to December 1998. From September 1996 through November 1997, he served as a financial consultant for high technology companies and was Acting Chief Financial Officer for Global Village Communications, Inc. From 1987 through June 1996 he served as Vice President and Chief Financial Officer of Margaux, Inc., a public company that manufactured refrigeration equipment. Mr. Lea received a B.S. degree in Agricultural Economics from the University of California, Davis and an M.B.A. from the University of California, Los Angeles.

*Dr. Madden* has served as Vice President, Chemical Operations since June 1998. From 1995 to June 1998, he served as Plant Manager and as Director of Process Development at Catalytica Pharmaceuticals, Inc., a contract pharmaceutical manufacturer. From 1977 to 1995, Dr. Madden served in a variety of positions with Syntex Corporation, a pharmaceutical company. His positions at Syntex included Technical Director at the Bahamas Chemical Division and Manager of Process Development and Engineering at the Technology Center in Boulder, Colorado. Dr. Madden received a B.A. degree in Chemistry from the University of Oxford and a Ph.D. from the University of London.

*Dr. Phan* has served as Vice President, Clinical Research since June 2003. Prior to that, Dr. Phan served as Director, Clinical Development from June 2000 to June 2003 and as Associate Director, Clinical Development from July 1998 to June 2000. Dr. Phan trained in Internal Medicine, Hematology and Medical Oncology at Stanford University. He is board certified in Internal Medicine and Medical Oncology. Dr. Phan received his M.D. from Columbia University College of Physicians and Surgeons and his B.S. degree in Molecular Biophysics and Biochemistry from Yale University.

*Dr. Renschler* has served as Vice President, Oncology Clinical Development since May 2001. Prior to that, Dr. Renschler served as Senior Director of Clinical Development from May 1998 to May 2001. Prior to that, Dr. Renschler served as Director of Clinical Development from January 1996 to May 1998. Dr. Renschler is also a Clinical Assistant Professor of Medicine/Oncology at Stanford University School of Medicine. He is board certified both in Medical Oncology and Internal Medicine. Dr. Renschler received his M.D. from Stanford University and a B.A. degree in Public and International Affairs from Princeton University.

*Mr. Gilburne* was elected as a Director of the company in March 2000. Mr. Gilburne has been a managing member of ZG Ventures, a venture capital and investment company since 2000. From February 1995 through December 1999, he was Senior Vice President, Corporate Development for America Online, Inc., an internet services company. He is currently a member of the board of directors of AOL Time Warner Inc. Prior to joining America Online, Mr. Gilburne was a founding partner of the Silicon Valley office of the law firm of Weil, Gotshal and Manges and a founding partner of the Cole Gilburne Fund, an early stage venture capital fund focused on information technology. Mr. Gilburne received an A.B. degree from Princeton University and a law degree from the Harvard Law School.

*Dr. Itri* was elected as a Director of the company in July 2001. She has served as President, Pharmaceutical Development, and Chief Medical Officer of Genta Incorporated, a biopharmaceutical company since May 2003. She joined Genta in March 2001 as Executive Vice President, Clinical Development and Chief Medical Officer. From November 1990 to January 2000 she was Senior Vice President, Worldwide Clinical Affairs, and Chief Medical Officer at Ortho Biotech Inc., a Johnson & Johnson Company. Dr. Itri earned her M.D. from New York Medical College, and is Board certified in Internal Medicine. She completed a fellowship in Medical Oncology at Memorial Sloan-Kettering Cancer Center.

*Dr. Levy* was elected as a Director of the company in June 2000. He has served as President and Chief Executive Officer and a director of Varian Medical Systems, Inc., a medical equipment company, since April 1999 and as its Chairman of the Board since February 2003, and as Executive Vice President of Varian Associates, Inc., the predecessor company from which Varian Medical Systems, Inc. was spun out, since 1992. Dr. Levy holds a B.A. degree from Dartmouth College and a Ph.D. in nuclear chemistry from the University of California at Berkeley.

*Mr. Rohn* was elected as a Director of the company in March 2000. He has served as the President and Chief Operating Officer of IDEC Pharmaceuticals Corporation, a biopharmaceutical company, since January 2002. He joined IDEC in August 1993 as Senior Vice President, Commercial and Corporate Development and was appointed Senior Vice President, Commercial Operations in April 1996 and Chief Operating Officer in May 1998. On June 23, 2003 IDEC announced its proposed merger with Biogen, Inc. The transaction remains subject to various closing conditions, including approval of the stockholders of IDEC and Biogen and other regulatory approvals and filings and is expected to be completed late in the third quarter or early in the fourth quarter of 2003. From 1984 to 1993, he was employed by Adria Laboratories, most recently as Senior Vice President of Sales and Marketing. Mr. Rohn is currently a Director of Cerus Corporation. Mr. Rohn received a B.A. in Marketing from Michigan State University.

*Mr. Taylor* was elected as a Director of the company in June 1991. Mr. Taylor is a General Partner of AMC Partners 89, L.P., and the General Partner of Asset Management Associates 1989, L.P., a private venture capital partnership. Mr. Taylor has been a Managing Member of Alloy Ventures, a venture management firm which succeeded Asset Management Company (the prior management firm for the Asset Management funds), since 1998. Mr. Taylor had been with Asset Management Company from 1977 to 1998, as General Partner since 1982. Mr. Taylor is a Director of Lynx Therapeutics, Inc. and several private companies. Mr. Taylor holds B.S. and M.S. degrees in Physics from Brown University and an M.B.A. from Stanford University.

**Item 2. *Properties***

Our corporate offices are located in Sunnyvale, California, where we lease approximately 90,000 square feet under two leases that expire in December 2003 and December 2007. We have subleased 18,000 square feet of this space through December 2003. These facilities include administrative and research and development space. Both leases are non-cancelable operating leases. We believe that our existing facilities are adequate to meet our current and foreseeable needs or that suitable additional space will be available as needed.

**Item 3. *Legal Proceedings***

None.

**Item 4. *Submission of Matters to a Vote of Security Holders***

None.

## PART II

### Item 5. *Market for Registrant's Common Equity and Related Stockholder Matters*

Our common stock began trading publicly on the Nasdaq Stock Market on October 24, 1995 and is traded under the symbol "PCYC." Prior to that date, there was no public market for our common stock. The following table sets forth for the periods indicated the high and low sales prices of the common stock.

	<u>HIGH</u>	<u>LOW</u>
FISCAL YEAR ENDED JUNE 30, 2002		
First Quarter . . . . .	\$ 34.01	\$ 14.54
Second Quarter . . . . .	28.12	8.80
Third Quarter . . . . .	10.94	6.60
Fourth Quarter . . . . .	8.00	4.00
FISCAL YEAR ENDED JUNE 30, 2003		
First Quarter . . . . .	\$ 4.72	\$ 2.77
Second Quarter . . . . .	3.65	2.35
Third Quarter . . . . .	4.12	2.98
Fourth Quarter . . . . .	5.70	3.07

As of June 30, 2003, there were 163 holders of record of our common stock. We have not paid cash dividends on our common stock since our inception and we do not anticipate paying any in the foreseeable future.

# **Item 6. Selected Financial Data**

The data set forth below should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and the financial statements and related notes included elsewhere herein.

	Years Ended June 30,					Period from Inception (April 1991) through June 30, 2003
	2003	2002	2001	2000	1999	
(in thousands, except per share amounts)						
STATEMENT OF OPERATIONS DATA:						
Revenues:						
License, milestone and grant revenues .....	\$ —	\$ —	\$ —	\$ 1,000	\$ 750	\$ 7,855
Contract revenues.....	—	—	3,121	604	1,291	5,847
Total revenues .....	—	—	3,121	1,604	2,041	13,702
Operating expenses:						
Research and development .....	23,912	33,981	37,974	28,590	21,889	197,479
Marketing, general and administrative	6,167	7,791	6,548	4,409	2,762	35,739
Total operating expenses .....	30,079	41,772	44,522	32,999	24,651	233,218
Loss from operations .....	(30,079)	(41,772)	(41,401)	(31,395)	(22,610)	(219,516)
Interest income .....	1,809	5,152	10,604	7,778	3,398	34,508
Interest expense and other income (expense), net .....	(28)	(45)	(128)	(13)	(34)	(1,557)
Net loss .....	<u>\$ (28,298)</u>	<u>\$ (36,575)</u>	<u>\$ (30,925)</u>	<u>\$ (23,630)</u>	<u>\$ (19,246)</u>	<u>\$ (186,565)</u>
Basic and diluted net						
loss per share(1) .....	<u>\$ (1.75)</u>	<u>\$ (2.27)</u>	<u>\$ (1.92)</u>	<u>\$ (1.60)</u>	<u>\$ (1.55)</u>	
Shares used to compute basic and						
diluted net loss per share(1) .....	<u>16,205</u>	<u>16,143</u>	<u>16,075</u>	<u>14,723</u>	<u>12,378</u>	

	June 30,				
	2003	2002	2001	2000	1999
(in thousands)					

## **BALANCE SHEET DATA:**

Cash, cash equivalents and marketable securities .....	\$ 87,735	\$ 114,918	\$ 152,782	\$ 178,247	\$ 50,005
Total assets .....	91,853	121,012	160,973	185,123	55,557
Capital lease obligations .....	—	—	—	59	275
Deficit accumulated during development stage .....	(186,565)	(158,267)	(121,692)	(90,767)	(67,137)
Total stockholders' equity .....	89,410	117,608	154,355	181,414	49,957

(1) See Note 1 to the financial statements for a description of the computation of basic and diluted net loss per share.

## **Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*In addition to historical information, this report contains predictions, estimates and other forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. Actual results could differ materially from any future performance suggested in this report as a result of the factors, including those discussed in "Risk Factors," elsewhere in this report.*

### **Overview**

Pharmacyclics is a pharmaceutical company focused on the development of products that improve existing therapeutic approaches to cancer and atherosclerosis. To date we have devoted substantially all of our resources to the research and development of our products and have not derived any commercial revenues from the sale of our products. We have two primary drug products, or research and development programs, for which we are currently focusing our efforts: Xcytrin® and Antrin®.

We have begun enrollment in a pivotal Phase 3 trial of Xcytrin for the potential treatment of lung cancer patients with brain metastases. This randomized controlled study, known as the SMART (Study of Neurologic Progression with Motexafin Gadolinium And Radiation Therapy) trial, will enroll about 550 patients; and we plan to complete enrollment in this trial in the fourth quarter of calendar 2004. The trial will compare the effects of whole brain radiation therapy (WBRT) alone to WBRT plus Xcytrin in lung cancer patients with brain metastases. The primary efficacy endpoint will be time to neurologic progression as determined by a blinded events-review committee. Survival and neurocognitive function will also be assessed as secondary endpoints of the trial. We requested and received a Special Protocol Assessment from the FDA for the SMART trial. Special Protocol Assessment provides for sponsors of clinical trials to receive official FDA evaluation, guidance and agreement on pivotal trials that will form the basis for final approval.

The SMART trial is based on the results of our completed large randomized trial in patients with brain metastases from solid tumors. That trial enrolled 401 patients and compared WBRT alone to WBRT plus Xcytrin. The primary end points were survival and time to neurologic progression. The overall trial did not meet its end points, but a benefit was seen in lung cancer, the largest sub-group of patients (N=251). There was an improvement in time to neurologic progression as assessed by investigators and by a blinded events review committee for lung cancer patients receiving Xcytrin. Lung cancer patients treated with Xcytrin were also found to have a reduction in death due to brain tumor progression as assessed by investigators and had improved time to neurocognitive progression.

We have completed patient enrollment in a multicenter Phase 2 trial with Xcytrin for the treatment of glioblastoma multiforme, a malignant primary brain tumor. We have begun Phase 2 clinical trials with Xcytrin used alone in hematologic cancers such as lymphoma. Phase 1 trials are underway evaluating Xcytrin given in combination with doxorubicin and with docetaxel (Taxotere®) for lung, prostate, ovarian and breast cancer and combined with radiation and chemotherapy for the treatment of newly diagnosed, advanced head and neck cancer patients. Through our Cooperative Research and Development Agreement, the National Cancer Institute is conducting Phase 1 trials of Xcytrin for treatment of both primary adult and pediatric brain tumors, pancreatic cancer and lung cancer.

We also completed a Phase 1 clinical trial with Antrin phototherapy for the treatment of coronary artery disease in patients receiving balloon angioplasty and stents. This study was primarily designed to evaluate the safety of various doses of drug and light. Results of this trial were published in the September 2003 issue of the journal *Circulation*. 79 patients were treated on this protocol, which demonstrated the safety and feasibility of Antrin phototherapy and determined optimum doses of drug and light for future trials. No major treatment-related angiographic or biochemical adverse effects or abnormalities were observed and no dose-limiting toxicities were noted. No instances of emergency coronary artery bypass, death, stroke or myocardial infarction occurred in patients who received both Antrin infusion and endovascular illumination and activation of the drug. The most frequently reported side effects were mild, transient rash and reversible mild tingling in the hands and feet, some of which lasted days to weeks, but did not require clinical intervention.

We have incurred significant operating losses since our inception in 1991, and as of June 30, 2003, had an accumulated deficit of approximately \$186.6 million. We expect to continue to incur significant operating losses until the commercialization of our products generates sufficient revenues to cover our expenses. We expect that losses will fluctuate from quarter to quarter and that such fluctuations may be substantial. Our achieving profitability depends upon our ability, alone or with others, to successfully complete the development of our products under development, and obtain required regulatory clearances and successfully manufacture and market our products. See "Risk Factors – All of our

product candidates are in development, and we cannot be certain that any of our products under development will be commercialized,” “- Acceptance of our products in the marketplace is uncertain, and failure to achieve market acceptance will harm our business,” “- We have a history of operating losses and we expect to continue to have losses in the future,” “- Failure to obtain product approvals or comply with ongoing governmental regulations could adversely affect our business” and “- Our capital requirements are uncertain and we may have difficulty raising needed capital in the future.”

## Results of Operations

### *Comparison of Years Ended June 30, 2003, 2002 and 2001*

**Revenues.** We had no revenues for the years ended June 30, 2003 and 2002, and revenues of \$3,121,000 for the year ended June 30, 2001. Revenues for the year ended June 30, 2001 resulted primarily from a non-recurring fee paid by Nycomed to terminate their collaboration agreement to sell and market a photodynamic therapy cancer product outside the United States, Canada and Japan and contract revenue received from Nycomed prior to the termination of the agreement.

**Research and Development Expenses.** Research and development expenses were \$23,912,000, \$33,981,000 and \$37,974,000 for the years ended June 30, 2003, 2002, and 2001, respectively. The \$10,069,000 decrease from 2002 to 2003 was primarily due to a reduction in headcount, the timing of clinical trial expenses related to our Xcytrin program and continued reduced spending on our Antrin program. The \$3,993,000 decrease from 2001 to 2002 was primarily due to decreased expenses with our Antrin program. Direct costs consist of personnel costs directly associated with a program, preclinical study costs, clinical trial costs, and related clinical drug and device development and manufacturing costs, drug formulation costs, contract services and other research expenditures. Indirect costs consist of personnel costs not directly associated with a program, overhead and facility costs and other support service expenses.

Research and development costs are identified as either directly attributed to one of our research and development programs or as an indirect cost, with only direct costs being tracked by specific program. Prior to 1999, we did not track our historical research and development costs by specific program. For this reason we cannot accurately estimate our total historical costs on a specific program basis. Direct costs by program and indirect costs are as follows:

<u>Program</u>	<u>2003</u>	<u>2002</u>	<u>2001</u>
Direct costs:			
Xcytrin .....	\$ 10,770,000	\$ 16,026,000	\$ 16,831,000
Antrin .....	1,241,000	3,968,000	8,437,000
Other .....	261,000	730,000	2,537,000
Total direct costs .....	12,272,000	20,724,000	27,805,000
Indirect costs .....	11,640,000	13,257,000	10,169,000
Total research and development costs .....	<u>\$ 23,912,000</u>	<u>\$ 33,981,000</u>	<u>\$ 37,974,000</u>

### Xcytrin

Xcytrin direct costs were \$10,770,000, \$16,026,000 and \$16,831,000 for the years ended June 30, 2003, 2002 and 2001, respectively. The decrease of \$5,256,000 in fiscal 2003 as compared to fiscal 2002 was primarily due to lower employee costs (\$2,446,000) as we reduced headcount in the second half of fiscal 2002, lower drug manufacturing costs (\$1,728,000) due to the timing of the manufacturing of Xcytrin, and lower consulting expenses (\$939,000). It is our policy to expense all costs related to the manufacture of our drug products when incurred until commercial viability of such products have been demonstrated and the necessary regulatory approvals have been received.

The decrease of \$805,000 in fiscal 2002 compared to fiscal 2001 was primarily due to lower clinical trial costs (\$2,317,000) as our Phase 3 trial was completed in fiscal 2002 and lower drug manufacturing costs (\$1,461,000) due to the timing of the manufacturing of Xcytrin. These decreases were partially offset by the increase in employee costs



(\$2,800,000) as we increased staffing to support the regulatory filings related to our initial Phase 3 clinical trial of Xcytrin.

#### Antrin

Antrin direct costs were \$1,241,000, \$3,968,000, and \$8,437,000 for the years ended June 30, 2003, 2002 and 2001, respectively. The decrease of \$2,727,000 in fiscal 2003 as compared to fiscal 2002 was primarily due to us continuing the trend of focusing our resources on our Xcytrin product. Fiscal 2003 efforts were focused on completing the clinical trials that were in process at the end of fiscal 2002. These efforts resulted in lower clinical trial costs (\$1,374,000), lower employee and travel costs (\$860,000) and lower consulting costs (\$221,000).

The decrease of \$4,469,000 in fiscal 2002 compared to fiscal 2001 was primarily due to focusing our resources on our Xcytrin product. This resulted in lower pre-clinical studies costs (\$1,427,000), lower employee costs (\$751,000) and lower device expenditures (\$595,000). Antrin direct costs in fiscal 2002 were also affected by lower drug manufacturing costs (\$998,000).

#### Other

Other direct costs were \$261,000, \$730,000, and \$2,537,000 for the years ended June 30, 2003, 2002 and 2001, respectively. The decreases in other direct costs year over year were primarily the result of decreased work on the company's photodynamic therapy cancer product.

#### Indirect Costs

Indirect costs were \$11,640,000, \$13,257,000 and \$10,169,000 for the years ended June 30, 2003, 2002 and 2001, respectively. The decrease of \$1,617,000 in fiscal 2003 as compared to 2002 was primarily due to reduced employee costs (\$789,000) due to a reduction in headcount in fiscal 2003 and reduced facility costs (\$494,000) as the company renegotiated one of its building leases to reduce the amount of leased space and the cost to lease the remaining space.

The increase of \$3,088,000 in fiscal 2002 as compared to fiscal 2001 was primarily due to the increase in facility and IT support costs (\$2,501,000) to support the growth in personnel and higher employee costs (\$885,000) as we increased headcount to support our research and development efforts, partially offset by lower consulting costs (\$253,000).

We expect slightly higher research and development costs in 2004 as compared to 2003. The higher costs will be primarily due to higher costs from our Phase 3 SMART Trial and due to additional Phase 1/2 trials for our Xcytrin product.

*Marketing, General and Administrative Expenses.* Marketing, general and administrative expenses for the years ended June 30, 2003, 2002 and 2001 were \$6,167,000, \$7,791,000 and \$6,548,000, respectively. The \$1,624,000 decrease in fiscal 2003 as compared to fiscal 2002 was primarily due to a decrease in marketing and market research expenses (\$1,029,000) as the company reduced such costs to focus resources on its Phase 3 clinical trial, lower employee costs (\$316,000) as the company reduced its headcount in fiscal 2003, and a reduction in consulting expenses (\$262,000) as the company utilized internal resources.

The \$1,243,000 increase in fiscal 2002 compared to fiscal 2001 primarily resulted from higher personnel costs (\$624,000) and higher facilities and IT support costs (\$627,000) to support expected increases in operations.

We expect fiscal 2004 marketing, general and administrative spending to remain consistent with 2003 levels.

*Interest and Other, Net.* Interest and other, net, was \$1,781,000, \$5,197,000 and \$10,476,000 for the years ended June 30, 2003, 2002 and 2001, respectively. The decreases in each of the past two fiscal years were primarily due to lower interest rates being earned on reduced balances of cash, cash equivalents and marketable securities. Our cash equivalents and marketable securities consist primarily of fixed rate instruments.

*Income Taxes.* At June 30, 2003, we had net operating loss carryforwards of approximately \$186.9 million for federal income tax reporting purposes and tax credit carryforwards of approximately \$7.6 million for federal reporting purposes. These amounts expire at various times through 2023. Under the Tax Reform Act of 1986, the amounts of and the benefit from net operating losses and tax credit carryforwards that can be carried forward may be impaired or limited in certain circumstances. These circumstances include, but are not limited to, a cumulative stock ownership change of greater than 50%, as defined, over a three year period. Such an annual limitation may result in the expiration of net oper-

ating losses before utilization. A full valuation allowance has been established for the company's deferred tax assets since realization of such assets through the generation of future taxable income is uncertain. See Note 5 of "Notes to Financial Statements."

### Liquidity and Capital Resources

Our principal sources of working capital have been private and public equity financings and proceeds from collaborative research and development agreements, as well as interest income. Since inception, we have used approximately \$173,198,000 of cash for operating activities and approximately \$14,246,000 of cash for the purchase of laboratory and office equipment and payments under capital lease agreements.

As of June 30, 2003, we had approximately \$87,735,000 in cash, cash equivalents and marketable securities. Net cash used in operating activities was \$27,144,000, \$36,324,000 and \$25,746,000 for the years ended June 30, 2003, 2002 and 2001, respectively, and resulted primarily from operating losses adjusted for non-cash expenses and changes in accounts payable, accrued liabilities, and prepaid expenses and other assets.

Net cash used by investing activities of \$11,915,000 in the year ended June 30, 2003 consisted primarily of purchases of marketable securities partially offset by proceeds from maturities and sales of marketable securities. Net cash provided by investing activities of \$73,590,000 and \$31,719,000 in the years ended June 30, 2002 and 2001, respectively, consisted primarily of proceeds of maturities and sales of marketable securities, net of purchases of marketable securities, partially offset by purchases of property and equipment.

Net cash provided by financing activities of \$106,000, \$667,000 and \$1,882,000 in the years ended June 30, 2003, 2002, and 2001, respectively, consisted primarily of proceeds from the exercise of stock options and the sale of stock under the company's employee stock purchase plan.

The company leases its facilities under non-cancelable operating leases that expire in fiscal 2008. Future minimum lease payments and sublease income under non-cancelable operating leases as of June 30, 2003 are as follows:

	Operating Lease Commitments	Operating Sublease Income
Fiscal 2004 .....	\$ 1,419,000	\$ (69,000)
Fiscal 2005 .....	1,162,000	—
Fiscal 2006 .....	1,201,000	—
Fiscal 2007 .....	1,220,000	—
Fiscal 2008 .....	610,000	—
Total minimum lease payments and operating sublease income .....	<u>\$ 5,612,000</u>	<u>\$ (69,000)</u>

Based upon the current status of our product development and commercialization plans, we believe that our existing cash, cash equivalents and marketable securities, will be adequate to satisfy our capital needs through at least fiscal year 2005. As discussed above under "Item 1 – Business – Cancer Therapy with Xcytrin", we expect to complete enrollment of our Phase 3 clinical trial of our first investigational drug Xcytrin in patients with brain metastases from non-small cell lung cancer in the fourth calendar quarter of 2004 (the second fiscal quarter of our fiscal 2005). There can be no assurance that our current capital resources will be sufficient to satisfy our capital needs through full enrollment of the Xcytrin trial or, if Xcytrin is ultimately approved for sale, through its production, marketing and commercialization. If our existing capital resources are insufficient to satisfy our capital requirements through testing, regulatory clearance and commercialization of Xcytrin, we would be required to raise additional funds through public or private financings, collaborative relationships (partnerships with other drug manufacturers) or other arrangements to complete commercialization. Our actual capital requirements will depend on many factors, including the status of product development; the time and cost involved in conducting clinical trials and obtaining regulatory approvals; filing, prosecuting and enforcing patent claims; competing technological and market developments; and our ability to market and distribute our products and establish new collaborative and licensing arrangements.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. The factors

described above will impact our future capital requirements and the adequacy of our available funds. If we are required to raise additional funds, we cannot be certain that such additional funding will be available on terms attractive to us, or at all. Furthermore, any additional equity financing may be dilutive to existing stockholders and debt financing, if available, may involve restrictive covenants. Collaborative arrangements, if necessary to raise additional funds, may require us to relinquish rights to certain of our technologies, products or marketing territories. Our failure to raise capital when needed could have a material adverse effect on our business, financial condition and results of operations. See "Risk Factors — Risks Related to Pharmacyclics — Our capital requirements are uncertain and we may have difficulty raising capital in the future."

### **Critical Accounting Policies**

Critical accounting policies are defined by the SEC as those that are most important to the portrayal of a company's financial condition and results, and that require management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effects of matters that are inherently uncertain. We have identified the following critical accounting policies used in the preparation of our financial statements and accompanying notes.

#### *Revenue Recognition*

Revenues are recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed and determinable and collectibility is reasonably assured. License and milestone fees are recognized as revenue when earned over the period of the arrangement, as evidenced by achievement of the specified milestones and the absence of any on-going obligation. License, milestone, contract and grant revenues are not subject to repayment. Any amounts received in advance of performance are recorded as deferred revenue.

#### *Cash Equivalents and Marketable Securities*

We maintain investment portfolio holdings of various issuers, types and maturities. We consider all highly liquid investments purchased with original maturities of three months or less to be cash equivalents. At June 30, 2003, these investment securities are classified as available-for-sale and consequently are recorded on the balance sheet at fair value with unrealized gains and losses reported as a separate component of accumulated other comprehensive income. Management assesses whether declines in the fair value of investment securities are other than temporary. If the decline in fair value is judged to be other than temporary, the cost basis of the individual security is written down to fair value and the amount of the write down is included in earnings. In determining whether a decline is other than temporary, management considers the following factors:

- Length of the time and the extent to which the market value has been less than cost;
- The financial condition and near-term prospects of the issuer;
- Our intent and ability to retain its investment in the issuer for a period of time sufficient to allow for any anticipated recovery in market value; and
- To date we have had no declines in fair value that have been identified as other than temporary.

### **Recently Issued Accounting Pronouncements**

In July 2002, the FASB issued SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*. SFAS 146 requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of a commitment to an exit or disposal plan. Examples of costs covered by the standard include lease termination costs and certain employee severance costs that are associated with a restructuring, discontinued operation, plant closing, or other exit or disposal activity. The company is required to adopt the provisions of SFAS 146 for exit or disposal activities initiated after December 31, 2002. The adoption of SFAS 146 did not have a material impact on the company's financial statements.

In November 2002, the FASB issued FASB Interpretation No. 45 ("FIN 45"), *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees and Indebtedness of Others*. FIN 45 elaborates on the disclosures to be made by the guarantor in its financial statements about its obligations under certain guarantees that it has issued. It also requires that a guarantor recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. The initial recognition and measurement provision of this inter-

pretation are applicable on a prospective basis to guarantees issued or modified after December 31, 2002, while provisions of the disclosure requirements are effective for financial statements ending after December 15, 2002. The adoption of FIN 45 did not have a material impact on the company's financial statements.

In May 2003, the FASB issued SFAS No. 150, *Accounting For Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. This Statement establishes standards for how an issuer classifies and measures in its statement of financial position certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances) because that financial instrument embodies an obligation of the issuer. This Statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003, except for mandatorily redeemable financial instruments of nonpublic entities. It is to be implemented by reporting the cumulative effect of a change in an accounting principle for financial instruments created before the issuance date of the Statement and still existing at the beginning of the interim period of adoption. The company does not expect that this standard will have a material impact on its financial statements.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

Our exposure to interest rate risk relates primarily to our investment portfolio. Fixed rate securities may have their fair market value adversely impacted due to fluctuations in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectations due to changes in interest rates or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates. The primary objective of our investment activities is to preserve principal while at the same time maximize yields without significantly increasing risk. To achieve this objective, we invest in debt instruments of the U.S. Government and its agencies and high-quality corporate issuers, and, by policy, restrict our exposure to any single corporate issuer by imposing concentration limits. To minimize the exposure due to adverse shifts in interest rates, we maintain investments at an average maturity of generally less than two years. Assuming a hypothetical increase in interest rates of one percentage point, the fair value of our total investment portfolio as of June 30, 2003 would have potentially declined by \$423,000.

**Item 8. *Financial Statements and Supplementary Data***

**INDEX TO FINANCIAL STATEMENTS**

	<b><u>Page</u></b>
Report of Independent Auditors .....	30
Balance Sheets .....	31
Statements of Operations .....	32
Statements of Cash Flows .....	33
Statements of Stockholders' Equity (Deficit) .....	34
Notes to Financial Statements .....	37

## REPORT OF INDEPENDENT AUDITORS

To the Board of Directors  
and Stockholders of Pharmacyclics, Inc.;

In our opinion, the accompanying balance sheets and the related statements of operations, of cash flows and of stockholders' equity (deficit) present fairly, in all material respects, the financial position of Pharmacyclics, Inc. (a development stage enterprise) at June 30, 2003 and 2002, and the results of its operations and its cash flows for each of the three years in the period ended June 30, 2003, and, cumulatively, for the period from inception (April 1991) through June 30, 2003, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP  
PricewaterhouseCoopers LLP

San Jose, California  
August 11, 2003

**PHARMACYCLICS, INC.**  
(a development stage enterprise)

**BALANCE SHEETS**  
(in thousands, except share and per share amounts)

	<u>June 30,</u>	
	<u>2003</u>	<u>2002</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	\$ 50,371	\$ 89,324
Marketable securities .....	37,364	25,594
Prepaid expenses and other current assets .....	1,339	1,182
Total current assets .....	89,074	116,100
Property and equipment, net .....	2,206	4,156
Other assets .....	573	756
	<u>\$ 91,853</u>	<u>\$ 121,012</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable .....	\$ 1,445	\$ 1,784
Accrued liabilities .....	963	1,386
Total current liabilities .....	2,408	3,170
Deferred rent .....	35	234
Total liabilities .....	<u>2,443</u>	<u>3,404</u>
Commitments (Note 2 and 6)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 1,000,000 shares authorized at June 30, 2003 and 2002; no shares issued and outstanding .....	—	—
Common stock, \$0.0001 par value; 49,000,000 shares authorized at June 30, 2003 and 2002; shares issued and outstanding -- 16,230,101 at June 30, 2003 and 16,187,796 at June 30, 2002 .....	2	2
Additional paid-in capital .....	275,829	275,710
Accumulated other comprehensive income .....	144	163
Deficit accumulated during development stage .....	(186,565)	(158,267)
Total stockholders' equity .....	89,410	117,608
	<u>\$ 91,853</u>	<u>\$ 121,012</u>

The accompanying notes are an integral part of these financial statements.

**PHARMACYCLICS, INC.**  
(a development stage enterprise)

**STATEMENTS OF OPERATIONS**  
(in thousands, except per share amounts)

	Year Ended June 30,			Period from Inception (April 1991) through June 30, 2003
	2003	2002	2001	
Revenues:				
License and milestone revenues	\$ —	\$ —	\$ —	\$ 7,855
Contract revenues	—	—	3,121	5,847
Total revenues	<u>—</u>	<u>—</u>	<u>3,121</u>	<u>13,702</u>
Operating expenses:				
Research and development	23,912	33,981	37,974	197,479
Marketing, general and administrative	6,167	7,791	6,548	35,739
Total operating expenses	<u>30,079</u>	<u>41,772</u>	<u>44,522</u>	<u>233,218</u>
Loss from operations	(30,079)	(41,772)	(41,401)	(219,516)
Interest income	1,809	5,152	10,604	34,508
Interest expense and other income (expense), net	(28)	45	(128)	(1,557)
Net loss	<u>\$ (28,298)</u>	<u>\$ (36,575)</u>	<u>\$ (30,925)</u>	<u>\$ (186,565)</u>
Basic and diluted net loss per share	<u>\$ (1.75)</u>	<u>\$ (2.27)</u>	<u>\$ (1.92)</u>	
Shares used to compute basic and diluted net loss per share	<u>16,205</u>	<u>16,143</u>	<u>16,075</u>	

The accompanying notes are an integral part of these financial statements.



**PHARMACYCLICS, INC.**  
**(a development stage enterprise)**  
**STATEMENTS OF CASH FLOWS**  
**(in thousands)**

	Year Ended June 30,			Period from Inception (April 1991) through June 30, 2003
	2003	2002	2001	
Cash flows from operating activities:				
Net loss .....	\$ (28,298)	\$ (36,575)	\$ (30,925)	\$ (186,565)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization .....	2,076	2,299	1,697	11,547
Stock compensation expense .....	13	91	326	850
Loss (gain) on sale of marketable securities .....	—	(20)	78	58
Write-down of fixed assets .....	—	16	47	381
Changes in assets and liabilities:				
Prepaid expenses and other assets .....	26	1,079	63	(1,912)
Accounts payable .....	(339)	(2,815)	1,748	1,445
Accrued liabilities .....	(423)	(475)	1,097	963
Deferred rent .....	(199)	76	123	35
Net cash used in operating activities .....	<u>(27,144)</u>	<u>(36,324)</u>	<u>(25,746)</u>	<u>(173,198)</u>
Cash flows from investing activities:				
Purchase of property and equipment .....	(126)	(1,297)	(3,122)	(10,365)
Proceeds from sale of property and equipment .....	—	—	—	112
Purchases of marketable securities .....	(42,462)	(49,059)	(43,208)	(388,451)
Proceeds from sales of marketable securities .....	4,000	8,517	8,795	21,312
Proceeds from maturities of marketable securities .....	26,673	115,429	69,254	329,861
Net cash provided by (used in) investing activities .....	<u>(11,915)</u>	<u>73,590</u>	<u>31,719</u>	<u>(47,531)</u>
Cash flows from financing activities:				
Issuance of common stock, net of issuance costs .....	106	667	1,941	251,467
Proceeds from notes payable .....	—	—	—	3,000
Issuance of convertible preferred stock, net of issuance costs .....	—	—	—	20,514
Payments under capital lease obligations .....	—	—	(59)	(3,881)
Net cash provided by financing activities .....	<u>106</u>	<u>667</u>	<u>1,882</u>	<u>271,100</u>
Increase (decrease) in cash and cash equivalents .....	(38,953)	37,933	7,855	50,371
Cash and cash equivalents at beginning of period .....	<u>89,324</u>	<u>51,391</u>	<u>43,536</u>	—
Cash and cash equivalents at end of period .....	<u>\$ 50,371</u>	<u>\$ 89,324</u>	<u>\$ 51,391</u>	<u>\$ 50,371</u>
Supplemental Disclosures of Cash Flow Information:				
Interest paid .....	\$ —	\$ —	\$ 6	\$ 1,269
Supplemental Disclosure of Non-Cash Investing and Financing Activities:				
Property and equipment acquired under capital lease obligations .....	—	—	—	3,881
Warrants issued .....	—	—	—	49
Conversion of notes payable and accrued interest into convertible preferred stock .....	—	—	—	3,051

The accompanying notes are an integral part of these financial statements.

**PHARMACYCLICS, INC.**  
(a development stage enterprise)

**STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**

For the period from inception (April 1991) through June 30, 2003  
(in thousands, except share and per share amounts)

	Convertible		Common Stock		Additional Paid-in Capital	Accumulated other Comprehensive Income/(Loss)	Deficit Accumulated During Development Stage	Total
	Shares	Amount	Shares	Amount				
Issuance of common stock for cash at \$0.02 per share	—	\$ —	400,000	\$ —	\$ 6	\$ —	—	\$ 6
Balance at June 30, 1991	—	—	400,000	—	6	—	—	6
Issuance of common stock for cash at an average price of \$0.02 per share	—	—	97,111	—	2	—	—	2
Issuance of convertible preferred stock for cash, net of issuance costs, at an average price of \$1.32 per share	2,040,784	—	—	—	2,667	—	—	2,667
Net loss	—	—	—	—	—	(523)	(523)	(523)
Balance at June 30, 1992	2,040,784	—	497,111	—	2,675	(523)	(523)	2,152
Issuance of common stock for cash at an average price of \$0.06 per share	—	—	49,000	—	3	—	—	3
Issuance of convertible preferred stock for cash, net of issuance costs, at \$4.88 per share	1,580,095	—	—	—	7,674	—	—	7,674
Net loss	—	—	—	—	—	(3,580)	(3,580)	(3,580)
Balance at June 30, 1993	3,620,879	—	546,111	—	10,352	(4,103)	(4,103)	6,249
Issuance of common stock upon exercise of stock options at an average price of \$0.12 per share	—	—	324,188	—	38	—	—	38
Issuance of convertible preferred stock for cash, net of issuance costs at an average price of \$8.63 per share	886,960	—	—	—	7,623	—	—	7,623
Net loss	—	—	—	—	—	(5,141)	(5,141)	(5,141)
Balance at June 30, 1994	4,507,839	—	870,299	—	18,013	(9,244)	(9,244)	8,769
Issuance of common stock upon exercise of stock options at an average price of \$0.24 per share	—	—	38,403	—	9	—	—	9
Issuance of warrants	—	—	—	—	49	—	—	49
Net loss	—	—	—	—	—	(10,479)	(10,479)	(10,479)
Balance at June 30, 1995	4,507,839	—	908,702	—	18,071	(19,723)	(19,723)	(1,652)
Issuance of convertible preferred stock for notes payable and accrued interest at an average of \$8.63 per share	353,483	—	—	—	3,051	—	—	3,051
Issuance of convertible preferred stock for cash, net of issuance costs, at an average price of \$8.63 per share	295,649	—	—	—	2,550	—	—	2,550
Issuance of common stock upon initial public offering, net of issuance costs, for cash at \$12 per share	—	—	2,383,450	1	26,042	—	—	26,043
Conversion of convertible preferred stock into common stock	(5,156,971)	—	5,156,971	—	—	—	—	—
Issuance of common stock upon exercise of stock options at an average exercise price of \$1.33 per share	—	—	91,922	—	122	—	—	122
Issuance of common stock upon exercise of purchase rights at an exercise price of \$10.20 per share	—	—	8,379	—	86	—	—	86

The accompanying notes are an integral part of these financial statements.

**PHARMACYCLICS, INC.**  
(a development stage enterprise)

**STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**

For the period from inception (April 1991) through June 30, 2003  
(in thousands, except share and per share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated other Comprehensive Income/(Loss)	Deficit Accumulated During Development Stage	Total
	Shares	Amount	Shares	Amount				
Stock compensation expense .....	—	—	—	—	26	—	—	26
Net loss .....	—	—	—	—	—	—	(8,235)	(8,235)
Balance at June 30, 1996 .....	—	—	—	—	49,948	—	(27,958)	21,991
Issuance of common stock, net of issuance costs, for cash at an average price of \$16.93 per share .....	—	—	8,549,424	—	—	—	—	—
Issuance of common stock upon exercise of stock options at an average price of \$2.74 per share .....	—	—	1,442,190	—	24,420	—	—	24,420
Issuance of common stock upon exercise of purchase rights at an exercise price of \$10.51 per share .....	—	—	96,283	—	264	—	—	264
Stock compensation expense .....	—	—	—	—	—	—	—	—
Net loss .....	—	—	—	—	—	—	—	—
Balance at June 30, 1997 .....	—	—	10,102,454	—	74,911	—	(10,258)	126
Issuance of common stock, net of issuance costs, for cash at \$21.75 per share .....	—	—	2,012,500	—	40,796	—	(38,216)	36,696
Issuance of common stock upon exercise of stock options at an average price of \$6.57 per share .....	—	—	88,933	—	584	—	—	584
Issuance of common stock upon exercise of purchase rights at an exercise price of \$14.36 per share .....	—	—	10,372	—	149	—	—	149
Issuance of common stock upon exercise of warrants .....	—	—	80,033	—	91	—	—	91
Stock compensation expense .....	—	—	—	—	—	—	—	—
Net loss .....	—	—	—	—	—	—	(9,675)	(9,675)
Balance at June 30, 1998 .....	—	—	12,294,292	—	116,531	—	(47,891)	68,641
Issuance of common stock upon exercise of stock options at an average price of \$5.10 per share .....	—	—	75,275	—	384	—	—	384
Issuance of common stock upon exercise of purchase rights at an exercise price of \$12.77 per share .....	—	—	13,643	—	174	—	—	174
Issuance of common stock upon exercise of warrants .....	—	—	45,661	—	89	—	—	89
Stock compensation expense .....	—	—	—	—	—	—	—	—
Comprehensive (loss): .....	—	—	—	—	—	(85)	—	(85)
Change in unrealized loss on marketable securities .....	—	—	—	—	—	—	(19,246)	(19,246)
Net loss .....	—	—	—	—	—	—	(67,137)	(67,137)
Balance at June 30, 1999 .....	—	—	12,428,871	—	117,178	—	—	49,957
Issuance of common stock upon exercise of stock options at an average price of \$13.88 per share .....	—	—	102,372	—	1,421	—	—	1,421

The accompanying notes are an integral part of these financial statements.

**PHARMACYCLICS, INC.**  
(a development stage enterprise)

**STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**

For the period from inception (April 1991) through June 30, 2003  
(in thousands, except share and per share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated other Comprehensive Income/(Loss)	Deficit Accumulated During Development Stage	Total
	Shares	Amount	Shares	Amount				
Issuance of common stock upon exercise of purchase rights at an exercise price of \$25.62 per share	—	—	11,213	—	287	—	—	287
Issuance of common stock, net of issuance costs, for cash at an average price of \$44.36 per share	—	—	3,465,000	1	153,711	—	—	153,712
Stock compensation expense	—	—	—	—	88	—	—	88
Comprehensive (loss):								
Change in unrealized loss on marketable securities	—	—	—	—	—	(421)	—	(421)
Net loss	—	—	—	—	—	—	(23,630)	(23,630)
Balance at June 30, 2000	—	—	16,007,456	2	272,685	(506)	(90,767)	181,414
Issuance of common stock upon exercise of stock options at an average price of \$16.17 per share	—	—	93,528	—	1,512	—	—	1,512
Issuance of common stock upon exercise of purchase rights at an exercise price of \$27.89 per share	—	—	15,386	—	429	—	—	429
Stock compensation expense	—	—	—	—	326	—	—	326
Comprehensive income:								
Change in unrealized gain on marketable securities	—	—	—	—	—	1,599	—	1,599
Net loss	—	—	—	—	—	—	(30,925)	(30,925)
Balance at June 30, 2001	—	—	16,116,370	2	274,952	1,093	(121,692)	154,355
Issuance of common stock upon exercise of stock options at an average price of \$13.93 per share	—	—	13,257	—	183	—	—	183
Issuance of common stock upon exercise of purchase rights at an exercise price of \$8.32 per share	—	—	58,169	—	484	—	—	484
Stock compensation expense	—	—	—	—	91	—	—	91
Comprehensive loss								
Change in unrealized gain on marketable securities	—	—	—	—	—	(930)	—	(930)
Net loss	—	—	—	—	—	—	(36,575)	(36,575)
Balance at June 30, 2002	—	—	16,187,796	2	275,710	163	(158,267)	117,608
Issuance of common stock upon exercise of stock options at an average price of \$1.03 per share	—	—	3,397	—	3	—	—	3
Issuance of common stock upon exercise of purchase rights at an exercise price of \$2.64 per share	—	—	38,908	—	103	—	—	103
Stock compensation expense	—	—	—	—	13	—	—	13
Comprehensive loss:								
Change in unrealized gain on marketable securities	—	—	—	—	—	(19)	—	(19)
Net loss	—	—	—	—	—	—	(28,298)	(28,298)
Balance at June 30, 2003	—	\$ —	16,230,101	\$ 2	\$ 275,829	\$ 144	\$ (186,565)	\$ 89,410

The accompanying notes are an integral part of these financial statements.

**PHARMACYCLICS, INC.**  
**(a development stage enterprise)**

**NOTES TO FINANCIAL STATEMENTS**

**Note 1 — The Company and Significant Accounting Policies:**

*Description of the company*

Pharmacyclics, Inc. (the “company”) was incorporated in Delaware in 1991 and commenced operations during 1992 to develop and market pharmaceutical products to improve upon current therapeutic approaches to the treatment of cancer and atherosclerosis. Since inception, the company has been in the development stage, principally involved in research and development and other business planning activities, with no commercial revenues from product sales. Successful future operations depend upon the company’s ability to develop, to obtain regulatory approval for, and to commercialize its products. The company operates in one business segment.

*Management’s use of estimates and assumptions*

The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reported period. Actual results could differ from those estimates.

*Basic and diluted net loss per share*

Basic earnings per share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed using the weighted average number of common and potential common shares outstanding during the period. Potential common shares consist of shares issuable upon the exercise of stock options (using the treasury stock method). Options to purchase 4,177,798, 4,268,687 and 3,272,936 shares of common stock were outstanding at June 30, 2003, 2002 and 2001, respectively, but have been excluded from the computation of diluted net loss per share because their effect was anti-dilutive.

*Cash and cash equivalents*

All highly liquid investments purchased with an original maturity date of three months or less that are readily convertible into cash and have insignificant interest rate risk are considered to be cash equivalents. All other investments are reported as available-for-sale marketable securities.

*Marketable securities – available-for-sale*

The company has classified all its marketable securities as “available-for-sale.” Unrealized gains and losses on available-for-sale securities are included in other comprehensive income (loss). The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretions of discounts to maturity. Such amortization is included in interest income. Gains and losses on securities sold are recorded based on the specific identification method and are included in interest expense and other income (expense), net in the statement of operations.

The company's marketable securities consisted of the following (in thousands):

	<u>Amortized Cost</u>	<u>Net Unrealized Gains</u>	<u>Estimated Fair Value</u>
<b>June 30, 2003</b>			
Debt (state or political subdivision) . . . . .	\$ 31,184	\$ 118	\$ 31,302
Debt (corporate) . . . . .	6,036	26	6,062
	<u>\$ 37,220</u>	<u>\$ 144</u>	<u>\$ 37,364</u>
<b>June 30, 2002</b>			
Debt (state or political subdivision) . . . . .	\$ 10,459	\$ 22	\$ 10,481
Debt (corporate) . . . . .	14,972	141	15,113
	<u>\$ 25,431</u>	<u>\$ 163</u>	<u>\$ 25,594</u>

At June 30, 2003 and 2002, all of the company's debt investments are classified as short-term, as the company may choose not to hold its investments until maturity in order to take advantage of market conditions. Unrealized losses in 2003 and 2002 were not material and have therefore been netted against unrealized gains and losses, respectively. At June 30, 2003, the company's marketable securities had the following maturities (in thousands):

	<u>Amortized Cost</u>	<u>Estimated Fair Value</u>
Less than one year . . . . .	\$ 17,965	\$ 18,030
Between one and two years . . . . .	19,255	19,334
	<u>\$ 37,220</u>	<u>\$ 37,364</u>

#### *Concentration of credit risk*

Financial instruments that potentially subject the company to credit risk consist principally of cash, cash equivalents and marketable securities. The company places its cash, cash equivalents and marketable securities with high-credit quality financial institutions and invests in debt instruments of financial institutions, corporations and government entities with strong credit ratings. Management of the company believes it has established guidelines relative to credit quality, diversification and maturities that maintain safety and liquidity.

#### *Property and equipment*

Property and equipment are stated at cost. Depreciation is computed using the straight-line method over the shorter of the estimated useful lives of the assets, generally three to five years, or the lease term of the respective assets, if applicable. Amortization of leasehold improvements is computed using the straight-line method over the shorter of their estimated useful lives or lease terms.

#### *Long-lived assets*

The company identifies and records impairment losses on long-lived assets when events and circumstances indicate that the assets might be impaired. No significant impairment losses have been recorded to date with respect to the company's long-lived assets, which consist primarily of property and equipment and leasehold improvements.

#### *Revenue recognition*

Revenues are recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed and determinable and collectibility is reasonably assured. License and milestone fees

are recognized as revenue when earned over the period of the arrangement, as evidenced by achievement of the specified milestones and the absence of any on-going performance obligation. License, milestone, contract and grant revenues are not subject to repayment. Any amounts received in advance of performance are recorded as deferred revenue.

#### *Recently issued accounting pronouncements*

In July 2002, the FASB issued SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*. SFAS 146 requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of a commitment to an exit or disposal plan. Examples of costs covered by the standard include lease termination costs and certain employee severance costs that are associated with a restructuring, discontinued operation, plant closing, or other exit or disposal activity. The company is required to adopt the provisions of SFAS 146 for exit or disposal activities initiated after December 31, 2002. The adoption of SFAS 146 did not have a material impact on the company's financial statements.

In November 2002, the FASB issued FASB Interpretation No. 45 ("FIN 45"), *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees and Indebtedness of Others*. FIN 45 elaborates on the disclosures to be made by the guarantor in its financial statements about its obligations under certain guarantees that it has issued. It also requires that a guarantor recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. The initial recognition and measurement provision of this interpretation are applicable on a prospective basis to guarantees issued or modified after December 31, 2002, while provisions of the disclosure requirements are effective for financial statements ending after December 15, 2002. The adoption of FIN 45 did not have a material impact on the company's financial statements.

In May 2003, the FASB issued SFAS No. 150, *Accounting For Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. This Statement establishes standards for how an issuer classifies and measures in its statement of financial position certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances) because that financial instrument embodies an obligation of the issuer. This Statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003, except for mandatorily redeemable financial instruments of nonpublic entities. It is to be implemented by reporting the cumulative effect of a change in an accounting principle for financial instruments created before the issuance date of the Statement and still existing at the beginning of the interim period of adoption. The company does not expect that this standard will have a material impact on its financial statements.

#### *Inventories*

The company has purchased quantities of its texaphyrin-based drug substance that are expected to be available in the future to support the commercial launch of its products currently under development. Until the commercial viability of such products has been demonstrated and the necessary regulatory approvals received, the company will continue to charge all such amounts to research and development expense.

#### *Research and development*

Research and development activities are expensed as incurred and include costs associated with company's internal programs, as well as costs incurred in connection with contract research performed pursuant to collaborative agreements. Research and development costs consist of direct and indirect internal costs related to specific projects as well as fees paid to other entities which conduct certain research activities on behalf of the company. Research and development expenses incurred in connection with research contracts were zero for the years ended June 30, 2003 and 2002 and \$0.9 million for the year ended June 30, 2001.

#### *Income taxes*

The company provides for income taxes using the liability method. This method requires that deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the tax bases of assets and liabilities and their financial statement reported amounts. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

### *Fair value of financial instruments*

The carrying value of the company's financial instruments including cash and cash equivalents, marketable securities and accrued liabilities, approximate fair value due to their short maturities.

### *Accounting for stock-based compensation*

During the year ended June 30, 2003, the company adopted Statement of Financial Accounting Standards No. 148, *Accounting for Stock-Based Compensation Disclosure*. The company accounts for stock-based employee compensation arrangements in accordance with the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB 25"), Financial Accounting Standards Board Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation – an Interpretation of APB No. 25* ("FIN 44") and complies with the disclosure provisions of Statement of Financial Accounting Standard No. 123, *Accounting for Stock-Based Compensation* ("SFAS No. 123") as amended by SFAS No. 148.

Under APB 25, compensation expense is based on the difference, if any, on the date of the grant, between the fair value of the company's stock and the exercise price. SFAS No. 123 defines a "fair value" based method of accounting for an employee stock option or similar equity instruments.

The weighted average estimated grant date fair value, as defined by SFAS 123, for options granted under the company's stock option plans during fiscal 2003, 2002 and 2001 was \$3.17, \$6.50 and \$23.43 per share, respectively. The weighted average estimated grant date fair value of purchase awards under the company's Purchase Plan during fiscal 2003, 2002 and 2001 was \$15.06, \$15.74 and \$21.09 per share, respectively. The estimated grant date fair values were calculated using the Black-Scholes valuation model.

The following assumptions are included in the estimated grant date fair value calculations for the company's stock option and purchase awards:

	Year Ended June 30,		
	2003	2002	2001
Stock option plans:			
Expected dividend yield . . . . .	0%	0%	0%
Expected stock price volatility . . . . .	89%	89%	84%
Risk free interest rate . . . . .	2.64%	4.72%	5.21%
Expected life (years) . . . . .	5.65	5.65	5.65
Stock purchase plan:			
Expected dividend yield . . . . .	0%	0%	0%
Expected stock price volatility . . . . .	98%	96%	81%
Risk free interest rate . . . . .	2.49%	2.94%	6.42%
Expected life (years) . . . . .	2.00	2.00	2.00

The following table illustrates the effect on net loss per common share if the company had applied the fair-value recognition provisions of SFAS No. 123 to stock-based employee compensation (in thousands, except per share amounts):

	Year Ended June 30,		
	2003	2002	2001
Net loss			
As reported . . . . .	\$ (28,298)	\$ (36,575)	\$ (30,925)
Deduct stock-based employee compensation expense determined under fair value based method . . . . .	(9,756)	(12,396)	(10,753)
Pro forma net loss . . . . .	<u>\$ (38,054)</u>	<u>\$ (48,971)</u>	<u>\$ (41,678)</u>
Basic and diluted net loss per common share:			
As reported . . . . .	\$ (1.75)	\$ (2.27)	\$ (1.92)
Pro forma . . . . .	<u>\$ (2.35)</u>	<u>\$ (3.03)</u>	<u>\$ (2.59)</u>



Such pro forma disclosure may not be representative of future compensation cost because options vest over several years and additional grants are anticipated each year.

The company accounts for equity instruments issued to non-employees for goods or services in accordance with the provisions of SFAS No. 123 and Emerging Task Force Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* ("EITF 96-18"). Accordingly, as these instruments vest, the company will be required to remeasure the fair value of the equity instruments at each reporting period prior to vesting and then finally at the vesting date of the equity instruments. Compensation expense under such agreements has been immaterial for the years ended June 30, 2003, 2002 and 2001.

## Note 2 — Agreements:

*University of Texas License.* The company has entered into two exclusive patent license agreements with The University of Texas which permit the company to exclusively manufacture, use and sell products covered by patents that result from certain research conducted by The University of Texas. Each agreement requires the company to pay royalties to The University of Texas. The company paid \$50,000, \$50,000 and \$100,000 of royalties in the years ended June 30, 2003, 2002 and 2001, respectively.

*Nycomed Collaboration.* In October 1997, the company entered into an agreement with Nycomed Imaging A/S, in which Nycomed acquired exclusive sales and marketing rights to the company's photodynamic therapy cancer product in all markets of the world excluding the United States, Canada and Japan. In May 2001, the company and Nycomed terminated this agreement. Pursuant to the termination agreement, Pharmacyclics reacquired all its rights from Nycomed to develop and market this product and Nycomed agreed to make a non-recurring termination payment to Pharmacyclics of \$2,750,000. The termination payment was recorded as revenue in the fourth quarter of fiscal 2001 as the company had no further performance obligation under the termination agreement.

## Note 3 — Balance Sheet Components:

Property and equipment consists of the following (in thousands):

	June 30,	
	2003	2002
Equipment . . . . .	\$ 6,795	\$ 7,165
Leasehold improvements . . . . .	4,014	4,044
Furniture and fixtures . . . . .	858	1,193
	11,667	12,402
Less accumulated depreciation and amortization. . . .	(9,461)	(8,246)
	<u>\$ 2,206</u>	<u>\$ 4,156</u>

Accrued liabilities consist of the following (in thousands):

	June 30,	
	2003	2002
Employee compensation . . . . .	\$ 896	\$ 1,319
Leasehold improvements . . . . .	67	67
	<u>\$ 963</u>	<u>\$ 1,386</u>

## Note 4 — Stockholders' Equity:

### Common stock

In September and October 1999, the company sold a total of 2,645,000 shares of its common stock at \$38.75 per share resulting in net cash proceeds of approximately \$96.1 million. In March 2000, the company sold 820,000 shares of common stock to four purchasers in a private placement. The shares were sold at \$73.25 per share, which resulted in net proceeds of approximately \$57.6 million.

### *Preferred stock*

As amended, the company's Certificate of Incorporation authorizes 1,000,000 shares of preferred stock, par value \$0.0001 per share. The Board of Directors is authorized to issue the preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof, including dividend rights, dividend rates, conversion rights, voting rights, terms of redemption, redemption prices, liquidation preferences and the number of shares constituting any series or the designation of such series, without further vote or action by the stockholders.

The ability of the company's Board of Directors to issue shares of preferred stock without stockholder approval, and the existence of the company's stockholder rights plan, may alone or in combination have certain anti-takeover effects. The company is also subject to provisions of the Delaware General Corporation Law, which may make certain business combinations more difficult.

### *Shareholder rights plan*

In April 1997, the Board of Directors approved a shareholder rights plan (the "Plan") under which stockholders of record on May 1, 1997 received a right to purchase (a "Right") one one-hundredth of a share of Series A Junior Participating Preferred Stock, par value \$.001 per share (the "Series A Preferred Stock"), at an exercise price of \$125 per one one-hundredth of a share, subject to adjustment. The Rights will separate from the common stock and Rights certificates will be issued and will become exercisable upon the earlier of (i) 10 business days following a public announcement that a person or group of affiliated or associated persons has acquired, or obtained the right to acquire, beneficial ownership of 15% or more of the company's outstanding common stock or (ii) 10 business days or such later date as may be determined by a majority of the Board of Directors following the commencement of, or announcement of, an intention to make a tender offer or exchange offer, the consummation of which would result in the beneficial ownership by a person or group of 15% or more of the outstanding common stock of the company. The Rights expire at the close of business on April 30, 2007. The company has designated 120,000 shares of its preferred stock as Series A Junior Participating Preferred Stock in connection with this plan. In December 2001, the Board of Directors approved an amendment to the Plan so that each Right entitles the holder to purchase one one-thousandth of a share of Series A Preferred Stock at a price of \$125 per one one-thousandth of a share, subject to adjustment.

### *Warrants*

In connection with the company's initial public offering during 1995, outstanding warrants to purchase shares of preferred stock were converted into warrants to purchase shares of common stock. In fiscal 1998, holders of all of the warrants granted in July 1995 elected "net issue exercises" at an average market price of \$24.15 per share, resulting in the issuance of 80,033 shares of common stock and the cancellation of warrants to purchase 44,465 shares of common stock. In fiscal 1999, warrants for 45,661 shares were exercised. At June 30, 2003 and 2002, there were no outstanding warrants.

### *Stock option plans*

**1992 Stock Option Plan.** The 1992 Stock Option Plan (the "1992 Plan"), as amended, authorizes the Board of Directors to grant incentive stock options and non-statutory stock options to employees, directors and consultants to purchase up to 1,233,334 shares of common stock. Under the 1992 Plan, incentive stock options are granted at a price not less than 100% of the estimated fair value of the stock on the date of grant, as determined by the Board of Directors. Nonqualified stock options are granted at a price not less than 85% of the estimated fair value of the stock on the date of grant, as determined by the Board of Directors. To date, all options granted under the 1992 Plan have been granted at 100% of the estimated fair value of the common stock as determined by the Board of Directors. Options are exercisable for a period of ten years.

**1995 Stock Option Plan.** The company's 1995 Stock Option Plan (the "1995 Plan") was adopted by the Board of Directors in August 1995. The 1995 Plan authorizes for issuance 4,347,754 shares of common stock. Beginning on January 1, 1996, the 1995 Plan also allows for an annual increase to the number of shares available for issuance equal to 1% of the number of shares of common stock outstanding on the last day of the preceding calendar year, not to exceed 500,000 shares per year. Shares of common stock subject to outstanding options that expire or terminate prior to exercise will be available for future issuance under the 1995 Plan.

Under the 1995 Plan, employees, non-employee members of the Board of Directors (other than those serving as members of the Compensation Committee) and independent consultants may, at the discretion of the plan administrator, be granted options to purchase shares of common stock at an exercise price not less than 85% of the fair market value of such shares on the grant date. Non-employee members of the Board of Directors will also be eligible for automatic option grants under the company's 1995 Non-Employee Directors Stock Option Plan. Generally, shares subject to options under the 1995 Plan vest over a four or five year period and are exercisable for a period of ten years.

In the event the company is acquired by merger, consolidation or asset sale, options outstanding under the 1995 Plan will immediately vest in full, except to the extent the options are assumed by the acquiring entity. Any assumed options will accelerate upon the optionee's involuntary termination within 18 months following the acquisition. The Compensation Committee also has discretion to provide for the acceleration of one or more outstanding options under the 1995 Plan and the vesting of shares subject to outstanding options upon the occurrence of certain hostile tender offers. Such accelerated vesting may be conditioned upon the subsequent termination of the affected optionee's service. The Board may amend or modify the 1995 Plan at any time. The 1995 Plan will terminate on August 1, 2005, unless terminated earlier by the Board.

*1995 Non-Employee Directors Stock Option Plan.* The company's 1995 Non-Employee Directors Stock Option Plan (the "Directors Plan"), was adopted by the Board of Directors on August 2, 1995. Automatic option grants are made at periodic intervals to eligible non-employee Board members under the Directors Plan. The Directors Plan became effective as of the effective date of the company's initial public offering. A total of 246,667 shares of common stock have been reserved for issuance under the Directors Plan.

Each individual first elected or appointed as a non-employee Board member will automatically be granted, on the date of such election or appointment, a non-statutory option to purchase 10,000 shares of common stock vesting over five years. In addition, on the date of each annual stockholders meeting each individual who is to continue to serve as a non-employee Board member after that annual meeting and has been a member of the Board for at least six months will automatically be granted a non-statutory option to purchase 5,000 shares of common stock. There will be no limit on the number of such annual 5,000-share option grants any one non-employee Board member may receive over his or her period of continued Board service. The exercise price per share of each automatic option grant will be equal to the fair market value of the common stock on the automatic grant date. Each automatic option will be immediately exercisable; however, any shares purchased upon exercise of the option will be subject to repurchase should the optionee's service as a non-employee Board member cease prior to vesting in the shares. Each 10,000-share grant will vest in five equal and successive annual installments over the optionee's period of Board service. Each 5,000-share grant will vest in twelve equal and successive monthly installments over the optionee's period of Board service.

In the event of the Board member's death or permanent disability or in the event the company is acquired by a merger or asset sale and in the event of certain hostile tender offers, each outstanding option will become fully vested. Upon the acquisition of 50% or more of the company's outstanding voting stock pursuant to a hostile tender offer, each automatic option grant outstanding for at least six months may be surrendered automatically or be cancelled in exchange for cash distribution to the Board member based upon the tender offer price. The Directors Plan will terminate on August 1, 2005.

The following table summarizes activity under the company's stock option plans (in thousands, except per share amounts):

	<u>Options Outstanding</u>		
	<u>Shares Available for Grant</u>	<u>Number</u>	<u>Weighted Average Exercise Price Per Share</u>
Authorized .....	1,000	—	\$ —
Granted .....	(480)	480	0.19
Balance at June 30, 1993 .....	520	480	0.19
Exercised .....	—	(324)	0.12
Granted .....	(167)	167	2.22
Canceled .....	8	(8)	0.11
Balance at June 30, 1994 .....	361	315	1.37
Exercised .....	—	(39)	0.24
Granted .....	(193)	193	3.75
Canceled .....	38	(38)	1.82
Balance at June 30, 1995 .....	206	431	2.50
Authorized .....	485	—	
Exercised .....	—	(92)	3.09
Granted .....	(492)	492	10.03
Canceled .....	11	(11)	6.11
Balance at June 30, 1996 .....	210	820	9.20
Authorized .....	842	—	
Exercised .....	—	(96)	2.74
Granted .....	(569)	569	16.69
Canceled .....	31	(31)	12.21
Balance at June 30, 1997 .....	514	1,262	11.58
Authorized .....	602	—	
Exercised .....	—	(89)	6.57
Granted .....	(577)	577	25.33
Canceled .....	158	(158)	15.41
Balance at June 30, 1998 .....	697	1,592	16.43
Authorized .....	524	—	
Exercised .....	—	(75)	5.10
Granted .....	(671)	671	19.25
Canceled .....	221	(221)	20.37
Balance at June 30, 1999 .....	771	1,967	17.38
Authorized .....	681	—	
Exercised .....	—	(103)	13.88
Granted .....	(723)	723	56.97
Canceled .....	53	(53)	23.38
Balance at June 30, 2000 .....	782	2,534	28.70
Authorized .....	811	—	
Exercised .....	—	(94)	16.17
Granted .....	(947)	947	36.80
Canceled .....	114	(114)	45.70
Balance at June 30, 2001 .....	760	3,273	29.78
Authorized .....	747	—	
Exercised .....	—	(13)	13.93
Granted .....	(1,634)	1,634	8.76
Canceled .....	625	(625)	27.83
Balance at June 30, 2002 .....	498	4,269	21.82
Authorized .....	162	—	
Exercised .....	—	(3)	1.03
Granted .....	(749)	749	4.35
Canceled .....	837	(837)	25.30
Balance at June 30, 2003 .....	748	4,178	18.03

A summary of outstanding and vested stock options as of June 30, 2003 is as follows:

Range of Exercise Prices	Options Outstanding			Options Vested	
	Number of Shares	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price Per Share	Number of Shares	Weighted Average Exercise Price Per Share
\$ 3.22 - \$ 4.25 .....	585,924	7.74	\$ 4.07	234,748	\$ 3.99
\$ 4.47 - \$ 4.47 .....	658,200	9.92	4.47	—	—
\$ 7.39 - \$ 7.39 .....	499,173	8.60	7.39	181,299	7.39
\$ 7.50 - \$16.00 .....	435,488	3.10	11.56	423,980	11.56
\$16.88 - \$18.07 .....	576,136	5.77	17.83	410,719	17.74
\$18.25 - \$27.00 .....	477,600	5.10	23.17	461,478	23.18
\$27.50 - \$36.25 .....	419,446	7.79	27.95	147,508	28.27
\$37.63 - \$78.13 .....	525,831	7.06	53.62	346,147	54.06
	<u>4,177,798</u>	<u>7.05</u>	<u>18.03</u>	<u>2,205,879</u>	<u>21.78</u>

The company has outstanding exercisable options to purchase 3,760,265, 3,774,694 and 3,081,532 shares of common stock with a weighted average exercise price of \$19.02, \$22.78 and \$28.84 at June 30, 2003, 2002, and 2001, respectively.

*Employee Stock Purchase Plan.* The company adopted an Employee Stock Purchase Plan (the "Purchase Plan") in August 1995. Qualified employees may elect to have a certain percentage of their salary withheld to purchase shares of the company's common stock under the Purchase Plan. The purchase price per share is equal to 85% of the fair market value of the stock on specified dates. Sales under the Purchase Plan in fiscal 2003, 2002 and 2001 were 38,908; 58,169 and 15,386 shares of common stock at an average price of \$2.64, \$8.32 and \$27.89 per share, respectively. Shares available for future purchase under the Purchase Plan are 329,373 at June 30, 2003. The Purchase Plan will terminate in October 2005.

#### Note 5 — Income Taxes:

Deferred tax assets are summarized as follows (in thousands):

	June 30,	
	2003	2002
Net operating loss carryforwards .....	\$ 66,787	\$ 56,981
Tax credit carryforwards .....	12,049	9,461
Capitalized start-up and R&D costs .....	4,477	3,560
Depreciation and amortization .....	911	847
Reserves and accruals .....	300	418
Gross deferred tax assets .....	84,524	71,267
Less valuation allowance .....	(84,524)	(71,267)
Net deferred tax assets .....	<u>\$ —</u>	<u>\$ —</u>

A full valuation allowance has been established for the company's deferred tax assets at June 30, 2003 and 2002 since realization of such assets through the generation of future taxable income is uncertain.

The provision for income taxes differs from the amount determined by applying the U.S. statutory income tax rate to the loss before income taxes as summarized below (in thousands):

	Year Ended June 30,		
	2003	2002	2001
Tax benefit at statutory rate .....	\$ 9,904	\$ 12,801	\$ 10,824
Net operating loss carryforward for .....	—	—	—
which no benefit was available .....	(9,904)	(12,801)	(10,824)
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

At June 30, 2003, the company had federal and state net operating loss carryforwards of approximately \$186.9 million and \$55.2 million, respectively, and federal and state tax credit carryforwards of \$7.6 million and \$6.6 million, respectively, available to offset future taxable income. These amounts expire at various times through 2023.

Under the Tax Reform Act of 1986, the amounts of and the benefit from net operating losses and tax credit carryforwards that can be carried forward may be impaired or limited in certain circumstances. These circumstances include, but are not limited to, a cumulative stock ownership change of greater than 50%, as defined, over a three year period. Such an annual limitation may result in the expiration of net operating losses before utilization.

#### Note 6 — Commitments:

The company leases its facilities under non-cancelable operating leases that expire in fiscal 2004 and 2008. Future minimum lease payments under non-cancelable operating leases are as follows (in thousands):

	<b>Operating Lease Commitments</b>	<b>Operating Sublease Income</b>
2004.....	\$ 1,419	\$ (69)
2005.....	1,162	—
2006.....	1,201	—
2007.....	1,220	—
2008.....	610	—
.....	<u>\$ 5,612</u>	<u>\$ (69)</u>

Rent expense for the years ended June 30, 2003, 2002 and 2001 was \$2,989,000, \$2,961,000 and \$1,174,000, respectively, and \$10,124,000 for the period from inception (April 1991) through June 30, 2003. Sublease income was \$369,000 and \$486,000 for the year ended June 30, 2003 and 2002, respectively, and \$855,000 from the period from inception (April 1991) through June 30, 2003. The terms of one facility lease provides for rental payments on a graduated scale. The company recognizes rent expense on a straight-line basis over the lease period and has accrued for rent expense incurred but not paid at June 30, 2003.

#### Note 7 — Quarterly Results (Unaudited)

The following table is in thousands, except per share amounts:

	<b>Quarter Ended</b>			
	<b>September 30,</b>	<b>December 31,</b>	<b>March 31,</b>	<b>June 30,</b>
<b>Fiscal 2003</b>				
Loss from operations.....	\$ (7,371)	\$ (7,316)	\$ (7,536)	\$ (7,856)
Net loss .....	(6,729)	(6,846)	(7,197)	(7,526)
Basic and diluted net loss per share .....	\$ (0.42)	\$ (0.42)	\$ (0.44)	\$ (0.46)
Shares used in computation of basic and diluted net loss per share .....	16,189	16,203	16,208	16,222
	<b>Quarter Ended</b>			
	<b>September 30,</b>	<b>December 31,</b>	<b>March 31,</b>	<b>June 30,</b>
<b>Fiscal 2002</b>				
Loss from operations .....	\$ (11,657)	\$ (13,105)	\$ (8,952)	\$ (8,058)
Net loss .....	(9,702)	(11,724)	(7,896)	(7,253)
Basic and diluted net loss per share .....	\$ (0.60)	\$ (0.73)	\$ (0.49)	\$ (0.45)
Shares used in computation of basic and diluted net loss per share .....	16,124	16,134	16,141	16,173

**Item 9. *Changes in and Disagreements With Auditors on Accounting and Financial Disclosure***

Not Applicable.

**Item 9A. *Controls and Procedures***

*(a) Evaluation of disclosure controls and procedures:* As required by rule 13a-15 under the Securities Exchange Act of 1934, as of the end of our fiscal year 2003 we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures. This evaluation was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are adequate and effective to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

*(b) Changes in internal controls over financial reporting:* There have been no changes (including corrective actions with regard to significant deficiencies or material weaknesses) in our internal controls over financial reporting that occurred during the latest fiscal quarter of 2003 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### PART III

**Item 10. Directors and Executive Officers of the Registrant**

The information required by this Item 10 (with respect to Directors and identification of Audit Committee) is hereby incorporated by reference from the information under the caption "Election of Directors" contained in the company's definitive proxy statement to be filed with the Securities and Exchange Commission no later than 120 days from the end of the Company's last fiscal year in connection with the solicitation of proxies for its Annual Meeting of Stockholders to be held on December 11, 2003, (the "Proxy Statement"). The required information concerning MANAGEMENT – Directors and Executive Officers is contained in Item 1, Part 1, of this Form 10-K under the caption "Executive Officers and Directors" on pages 18 through 19.

The information required by Section 16(a) is hereby incorporated by reference from the information under the caption "Compliance with Section 16(a) of the Securities Exchange Act of 1934" in the Proxy Statement.

**Item 11. Executive Compensation**

The information required by this Item 11 is incorporated by reference from the information under the caption "Election of Directors, Summary of Cash and Certain Other Compensation, Stock Options, Exercises and Holdings" in the Proxy Statement.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

**Equity Compensation Plan Information  
As of June 30, 2003**

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders (1) . .	4,177,798	\$ 18.03	1,076,782
Equity compensation plans not approved by security holders . . . . .	<u>—</u>	<u>—</u>	<u>—</u>
Total . . . . .	<u>4,177,798</u>	<u>\$ 18.03</u>	<u>1,076,782</u>

(1) Includes our 1992 Stock Option Plan, 1995 Stock Option Plan, 1995 Non-employee Directors Stock Option Plan, and Employee Stock Purchase Plan

The other information required by this Item 12 is incorporated by reference from the information under the caption "Stock Ownership of Management and Certain Beneficial Owners" in the Proxy Statement.

**Item 13. Certain Relationships and Related Transactions**

The information required by this Item 13 is incorporated by reference from the information under the caption "Certain Relationships and Related Transactions" in the Proxy Statement.



## PART IV

### Item 14. Principal Accountant Fees and Services

The information required by this Item 14 is incorporated by reference from the information in the Proxy Statement.

### Item 15. Financial Statement Schedules, Exhibits and Reports on Form 8-K

#### (a) 1. Financial Statements

See Index to Financial Statements under Item 8 on page 29.

#### (a) 2. Financial Statement Schedules

All schedules are omitted because they are not applicable or are not required or the information required to be set forth therein is included in the consolidated financial statement or notes thereto.

#### (b) Reports on Form 8-K

On May 1, 2003, we filed a Current Report on Form 8-K announcing our financial results for the fiscal quarter ended March 31, 2003.

#### (c) Exhibits

The following documents are incorporated by reference or included in this report.

<u>Exhibit Number</u>	<u>Description</u>
---------------------------	--------------------

- |       |   |
|-------|---|
| 3.1   | Amended and Restated Certificate of Incorporation of the Company (Incorporated by reference to exhibit of the same number to Form 8-A12G/A filed on May 21, 2002) . . . . .   |
| 3.2   | Amended and Restated Bylaws of the Company (Incorporated by reference to exhibit of the same number to the Quarterly Report on Form 10-Q for the quarter ended December 31, 2001). . . . .  |
| 3.3   | Certificate of Designation of Series A Junior Participating Preferred Stock of the Company (Incorporated by reference on Form 10-K for the fiscal year ended June 30, 1997) . . . . .   |
| 4.1   | Amended and Restated Rights Agreement, dated as of February 15, 2002 Incorporated by reference to Exhibit 3.2 to Form 8-A12G/A filed on May 21, 2002) . . . . .   |
| 4.2   | Specimen Certificate of the Company's Common Stock (Incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1, Commission File No. 33-96048) . . . . .   |
| 10.1  | Form of Indemnification Agreement between the Company and its directors and executive officers (Incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1, Commission File No. 33-96048) . . . . .  |
| 10.6* | Patent License Agreement entered into between the Company and The University of Texas, Austin entered into on or about July 1, 1991 (Incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1, Commission File No. 33-96048) . . . . .   |
| 10.7* | Patent License Agreement entered into between the Company and The University of Texas, Dallas dated as of July 1, 1992, as amended by the Patent License Agreement dated May 27, 1993 (Incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1, Commission File No. 33-96048) . . . . .           |
| 10.8* | Patent License Agreement entered into between the Company and Stuart W. Young dated as of October 15, 1992 (Incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1, Commission File No. 33-96048) . . . . .   |
| 10.9  | Lease Agreement entered into between the Company and New England Mutual Life Insurance Company dated as of June 17, 1993, as amended on July 22, 1993, and as further amended on March 1, 1994 (Incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1, Commission File No. 33-96048) . . . . . |

- 10.13+ The Company's 1995 Stock Option Plan (Incorporated by reference to Exhibit 99.1 to the Company's Registration Statement on Form S-8, Commission File No. 333-52881) .....
- 10.14+ The Company's 1995 Non-Employee Directors' Stock Option Plan (Incorporated by reference to Exhibit 99.7 to the Company's Registration Statement on Form S-8, Commission File No. 33-98514) .....
- 10.15+ The Company's Employee Stock Purchase Plan (Incorporated by reference to Exhibit 99.7 to the Company's Registration Statement on Form S-8, Commission File No. 333-52881) .....
- 10.16+ Employment Agreement entered into between the Company and Richard A. Miller, M.D. dated as of June 10, 1992 (Incorporated by reference to Exhibit 10.19 to the Company's Registration Statement on Form S-1, Commission File No. 33-96048) .....
- 10.22+ Form of Notice of Grant of Stock Option generally to be used under the 1995 Stock Option Plan (Incorporated by reference to Exhibit 99.2 to the Company's Registration Statement on Form S-8, Commission File No. 33-98514) .....
- 10.23+ Form of Stock Option Agreement (Incorporated by reference to Exhibit 99.3 to the Company's Registration Statement on Form S-8, Commission File No. 333-52881) .....
- 10.24+ Form of Addendum to Stock Option Agreement (Limited Stock Appreciation Right) (Incorporated by reference to Exhibit 99.4 to the Company's Registration Statement on Form S-8, Commission File No. 333-52881) ..
- 10.25+ Form of Addendum to Stock Option Agreement (Special Tax Election) (Incorporated by reference to Exhibit 99.5 to the Company's Registration Statement on Form S-8, Commission File No. 33-98514). ....
- 10.26+ Form of Addendum to Stock Option Agreement (Involuntary Termination following Change in Control) (Incorporated by reference to Exhibit 99.6 to the Company's Registration Statement on Form S-8, Commission File No. 33-98514) .....
- 10.27+ Form of Notice of Grant of Automatic Stock Option (Initial Grant) (Incorporated by reference to Exhibit 99.8 to the Company's Registration Statement on Form S-8, Commission File No. 33-98514) .....
- 10.28+ Form of Notice of Grant of Automatic Stock Option (Annual Grant) (Incorporated by reference to Exhibit 99.9 to the Company's Registration Statement on Form S-8, Commission File No. 33-98514) .....
- 10.29+ Form of Non-Employee Director Stock Option Agreement (Incorporated by reference to Exhibit 99.10 to the Company's Registration Statement on Form S-8, Commission File No. 33-98514) .....
- 10.30+ Form of Employee Stock Purchase Plan Enrollment/Change Form (Incorporated by reference to Exhibit 99.12 to the Company's Registration Statement on Form S-8, Commission File No. 33-98514) .....
- 10.31+ Form of Stock Purchase Agreement (Incorporated by reference to Exhibit 99.13 to the Company's Registration Statement on Form S-8, Commission File No. 33-98514) .....
- 10.35+ Form of Severance Agreement between the Company and certain executive officers (Incorporated by reference to exhibit of the same number to the Quarterly report on Form 0-Q for the quarter ended September 30, 1997)
- 10.38+ Employment Agreement, dated December 18, 1997, by and between the Company and Leiv Lea (Incorporated by reference to Exhibit 10.38 to the Quarterly report on Form 10-Q for the quarter ended March 31, 1998) ..
- 10.41+ Employment agreement, dated May 28, 1998, by and between the Company and Hugo Madden (Incorporated by reference to Exhibit 10.41 to the Annual Report on Form 10-K for the year ended June 30, 1999) .....
- 10.44\* Master Development and Supply Agreement, dated March 20, 2000 by and between Cook Imaging Corporation, D.B.A. Cook Pharmaceutical Solutions, and the Registrant (Incorporated by reference to Exhibit 10.1 to the Quarterly report on Form 10-Q for the quarter ended March 31, 2000) .....
- 10.47\* Supply Agreement, dated December 11, 2000 by and between Dixie Chemical Company and the Registrant (Incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q for the quarter ended December 31, 2000) .....
- 10.48\* Supply Agreement, dated December 18, 2000 by and between Lonza, AG and the Registrant (Incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q for the quarter ended December 31, 2000) ..

10.49	Lease and Lease Termination Agreement dated June 14, 2000 by and between the Registrant and Metropolitan Life Insurance Company (Incorporated by reference to Exhibit 10.49 to the Annual Report on Form 10-K for the year ended June 30, 2001) . . . . .
10.50	First Amendment to New Lease dated April 10, 2001 by and between the Registrant and Metropolitan Life Insurance Company (Incorporated by reference to Exhibit 10.50 to the Annual Report on Form 10-K for the year ended June 30, 2001). . . . .
10.51	Second Amendment to New Lease dated June 29, 2001 by and between the Registrant and Metropolitan Life Insurance Company (Incorporated by reference to Exhibit 10.51 to the Annual Report on Form 10-K for the year ended June 30, 2001). . . . .
10.52+	Employment agreement, dated August 14, 2001, by and between the Company and Timothy G. Whitten (Incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q for the quarter ended September 30, 2001) . . . . .
10.53*	Supply Agreement, dated August 17, 2001 by and between EMS-Dottikon AG and the Registrant (Incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q for the quarter ended September 30, 2001) . . . . .
10.54	Third Amendment to New Lease dated February 5, 2003 by and between the Registrant and Metropolitan Life Insurance Company (Incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q for the quarter ended March 31, 2003) . . . . .
23.1	Consent of Independent Accountants . . . . .
24.1	Power of Attorney (see page 52) . . . . .
31.1	Section 302 Certification of CEO . . . . .
31.2	Section 302 Certification of CFO . . . . .
32.1	Section 906 Certifications of CEO and CFO . . . . .

---

\* Confidential treatment has been granted as to certain portions of this agreement.

+ Indicates a management contract or compensatory plan or arrangement.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: September 25, 2003

PHARMACYCLICS, INC.

By: /s/ RICHARD A. MILLER, M.D.  
Richard A. Miller, M.D.  
President and Chief Executive Officer

POWER OF ATTORNEY KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints jointly and severally, Richard A. Miller and Leiv Lea, or either of them as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, each of the undersigned has executed this Power of Attorney as of the date indicated.

Pursuant to the requirements of the Exchange Act, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
<u>/s/ RICHARD A. MILLER, M.D.</u> Richard A. Miller, M.D.	President and Chief Executive Officer and Director (Principal Executive Officer)	September 25, 2003
<u>/s/ LEIV LEA</u> Leiv Lea	Vice President, Finance and Administration and Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)	September 25, 2003
<u>/s/ MILES R. GILBURNE</u> Miles R. Gilburne	Director	September 25, 2003
<u>/s/ LORETTA M. ITRI, M.D.</u> Loretta M. Itri, M.D.	Director	September 25, 2003
<u>/s/ RICHARD M. LEVY, PH.D.</u> Richard M. Levy, Ph.D.	Director	September 25, 2003
<u>/s/ WILLIAM R. ROHN</u> William R. Rohn	Director	September 25, 2003
<u>/s/ CRAIG C. TAYLOR</u> Craig C. Taylor	Director	September 25, 2003

## C O R P O R A T E   D I R E C T O R Y

### OFFICERS

**Richard A. Miller, M.D.**  
President & Chief Executive Officer

**Leiv Lea**  
Chief Financial Officer & Vice President,  
Finance & Administration and Secretary

**Timothy G. Whitten**  
Senior Vice President,  
Commercial Operations & Development

**Hugo Madden, Ph.D.**  
Vice President,  
Chemical Operations

**Markus F. Renschler, M.D.**  
Vice President,  
Oncology Clinical Development

**See-Chun Phan, M.D.**  
Vice President,  
Clinical Research

### BOARD OF DIRECTORS

**Richard A. Miller, M.D.**  
President & Chief Executive Officer

**Miles R. Gilburne**  
Managing Member  
ZG Ventures, LLC

**Loretta M. Itri, M.D.**  
President, Pharmaceutical Development  
& Chief Medical Officer  
Genta Incorporated

**Richard M. Levy, Ph.D.**  
Chairman & Chief Executive Officer  
Varian Medical Systems, Inc.

**William R. Rohn**  
President & Chief Operating Officer  
IDEC Pharmaceuticals Corporation

**Craig C. Taylor**  
Managing Member  
Alloy Ventures

### INDEPENDENT AUDITORS

PricewaterhouseCoopers LLP  
10 Almaden Blvd., Suite 1600  
San Jose, CA 95113

### ANNUAL STOCKHOLDERS MEETING

Pharmacyclics' annual meeting of  
stockholders will be held at 12:00 p.m.,  
on December 11, 2003, at the Sheraton  
Palo Alto Hotel, 625 El Camino Real,  
Palo Alto, CA 94301.

### COMMON STOCK INFORMATION

At June 30, 2003, there were approximately  
16,230,101 shares outstanding of  
Pharmacyclics common stock. Pharmacyclics'  
stock is traded on the Nasdaq Stock Market  
under the symbol: PCYC.

### COMPANY CONTACTS

**Leiv Lea**  
Chief Financial Officer & Vice President,  
Finance & Administration and Secretary  
(408) 774-0330

**Jim Weiss**  
Corporate Communications  
(408) 990-7295

### REGISTRAR AND TRANSFER AGENT

EquiServe Trust Company, N.A.  
P.O. Box 43023  
Providence, RI 02940-3023  
Shareholder Inquiries: (877) 282-1169  
Internet Address: <http://www.EquiServe.com>

### QUARTERLY REPORTING AND OTHER INFORMATION

Pharmacyclics' quarterly and annual reports,  
press releases and other information regarding  
the Company and its technology are available  
on the Internet: <http://www.pcy.com>

### FORM 10-K

Additional copies of the Company's Form 10-K,  
which is filed with the Securities and Exchange  
Commission, are available upon request,  
free of charge. Write to:  
Investor Relations  
Pharmacyclics, Inc.  
995 East Arques Avenue  
Sunnyvale, CA 94085-4521

EXCEPT FOR HISTORICAL INFORMATION CONTAINED HEREIN, THE MATTERS DISCUSSED IN THIS DOCUMENT ARE FORWARD-LOOKING STATEMENTS THAT INVOLVE RISKS AND UNCERTAINTIES, INCLUDING RISKS ASSOCIATED WITH THE PROGRESS AND OUTCOMES OF CLINICAL TRIALS AND PRECLINICAL STUDIES, PRODUCT DEVELOPMENT ACTIVITIES, THE ABILITY TO MARKET POTENTIAL PRODUCTS, PHARMACYCLICS' ABILITY TO BECOME A LEADING ONCOLOGY COMPANY AND SUCCESSFULLY COMMERCIALIZE NOVEL ONCOLOGY PRODUCTS, AND THE SUFFICIENCY OF OUR CASH POSITION. ACTUAL RESULTS AND TIMELINES MAY DIFFER MATERIALLY FROM THOSE PROJECTED AS A RESULT OF RISKS DETAILED IN PHARMACYCLICS' LATEST ANNUAL REPORT ON FORM 10-K AND ITS OTHER FILINGS WITH THE SECURITIES AND EXCHANGE COMMISSION. THESE FORWARD-LOOKING STATEMENTS REPRESENT THE COMPANY'S JUDGMENT AS OF THE DATE OF THIS DOCUMENT. THE COMPANY DISCLAIMS ANY INTENT OR OBLIGATION TO UPDATE FORWARD-LOOKING STATEMENTS. PHARMACYCLICS®, XCYTRIN®, ANTRIN® AND THE "PENTADENTE" LOGO® ARE REGISTERED TRADEMARKS OF PHARMACYCLICS, INC.

